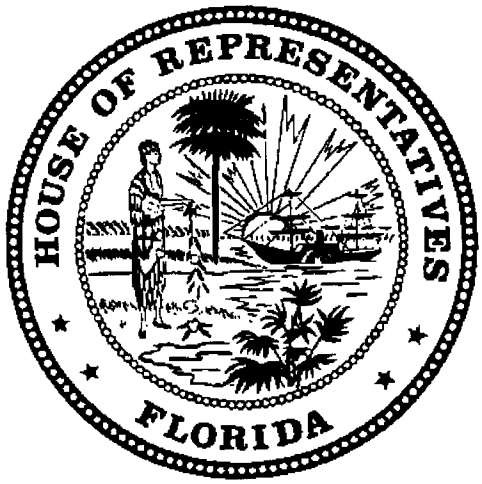


Health Care General Committee

Wednesday, March 8, 2006
10:00 AM – 12:00 PM
306 HOB

COMMITTEE MEETING PACKET

Allan G. Bense
Speaker

Gayle B. Harrell
Chair

AGENDA

Health Care General Committee
March 8, 2006
10:00 a.m. – 12:00 p.m.
306 HOB

I. Call to order/Roll Call

II. Opening Remarks

III. Consideration of the following bill:

- HB 1027 - - Biomedical Research by Hasner, Coley

IV. Workshop on the following:

- HB 645 - - Nursing Home Facilities by Gelber

V. Presentation of OPPAGA Report No. 06-07
Inflated Pricing, Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

VI. Presentation by the Department of Health
Crohn's Disease and Ulcerative Colitis Report

VII. Presentation by the Florida Council for Community Mental Health
Mental Health and Hospital Emergency Care

VIII. Closing Remarks and Adjournment

A bill to be entitled

An act relating to biomedical research; providing legislative intent; amending s. 215.5602, F.S.; revising the method for appointing members to the Biomedical Research Advisory Council; authorizing the Legislature to annually appropriate funds to the James and Esther King Biomedical Research Program; providing for transition to new appointments; amending s. 381.855, F.S.; revising the purpose of the Florida Center for Universal Research to Eradicate Disease; requiring the center to provide grants for cancer research; revising membership of the center's advisory council; providing for terms of office and the filling of vacancies; providing for officers, meetings, and procedure; providing procedures for awarding of cancer research grants; providing for peer review panels; providing requirements with respect to ethical conduct and conflicts of interest; providing for public records and meetings; authorizing the Legislature to annually appropriate funds to the Florida Center for Universal Research to Eradicate Disease; providing for transition to new appointments; amending s. 381.921, F.S.; revising a goal of the Florida Cancer Council; creating s. 381.922, F.S.; establishing the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program within the Department of Health; providing the purpose of the program; requiring an annual report; amending s. 561.121, F.S.; redistributing certain funds collected from taxes on alcoholic beverages; amending s. 1004.445, F.S.; revising

the method of appointing and filling vacancies on the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; requiring certain information in the annual report; requiring an annual operating budget; providing procedures for awarding of Alzheimer's disease research grants; providing for peer review panels; providing requirements with respect to ethical conduct, conflicts of interest, and confidentiality; providing for public records and meetings; authorizing the Legislature to annually appropriate funds to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; providing for transition to new appointments; providing appropriations; providing effective dates.

Be It Enacted by the Legislature of the State of Florida:

Section 1. It is the intent of the Legislature to provide funding to support grants for biomedical research in this state with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from diseases such as cancer and Alzheimer's disease. It is the intent of the Legislature to dramatically reduce this state's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in this state, making this state a world-class leader in cancer research and treatment. Further, it is the intent of the Legislature to address the debilitating and deadly effects

of Alzheimer's disease by supporting research in Alzheimer's disease statewide through the awarding of research grants on a competitive basis. Additionally, it is the intent of the Legislature to stimulate dramatic economic development, particularly in the biotechnology industry, through investment in this state's biomedical research.

Section 2. Subsection (3) of section 215.5602, Florida Statutes, is amended, and subsection (11) is added to that section, to read:

215.5602 James and Esther King Biomedical Research Program.--

(3) There is created within the Department of Health the Biomedical Research Advisory Council.

(a) The council shall consist of nine members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the Florida/Puerto Rico Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of Florida, or a designee. The ~~Governor shall appoint the~~ remaining six members of the council~~,~~ shall be appointed as follows:

1. The Governor shall appoint two members with expertise in the field of biomedical research, one member from a research university in the state, and one member representing the general population of the state.

2. The President of the Senate shall appoint one member with expertise in the field of behavioral or social research.

3. The Speaker of the House of Representatives shall appoint one member from a professional medical organization.

~~4. One member from a research university in the state.~~

~~5. One member representing the general population of the state.~~

In making these ~~his or her~~ appointments, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall select primarily, but not exclusively, Floridians with biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease. The ~~Governor's~~ appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed ~~A council~~ member ~~appointed by the Governor~~ may not serve more than two consecutive terms.

(b) The council shall adopt internal organizational procedures as necessary for its efficient organization.

(c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.

(d) Members of the council shall serve without compensation, but may receive reimbursement as provided in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties.

(11) The Legislature may annually appropriate funds to the James and Esther King Biomedical Research Program for the purposes of this section.

Section 3. All appointments to the Biomedical Research Advisory Council for the James and Esther King Biomedical Research Program that were not made in accordance with s. 215.5602, Florida Statutes, as amended by this act, shall expire June 30, 2006, but such appointees may continue to serve until their successors are appointed. This section shall take effect upon this act becoming a law.

Section 4. Subsections (3) and (5) of section 381.855, Florida Statutes, are amended, and subsections (6), (7), (8), and (9) are added to that section, to read:

381.855 Florida Center for Universal Research to Eradicate Disease.--

(3) There is established within the Department of Health the Florida Center for Universal Research to Eradicate Disease, which shall be known as "CURED."

(a) The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, including providing grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922, and foster improved technology transfer of research findings into clinical trials and widespread public use.

(b) The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, autoimmune disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

(c) The center shall hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures. Summit attendees shall cover the costs of such attendance or obtain sponsorship for such attendance.

(d) The center shall encourage clinical trials in this state on research that holds promise of curing a disease or condition. The center shall facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, placentas, or cord blood.

(e) The center shall facilitate the formation of partnerships between researchers in this state and institutions in other states and countries where research with rare plants or animals could lead to cures.

(f) The center shall encourage agricultural colleges and agricultural businesses in this state to be active in the search for cures and in providing information to the public about disease prevention.

(g) The center shall facilitate partnerships among researchers working to cure all types of diseases, including those that are prevalent in developed countries and those that occur mainly in developing countries.

(h) The center shall also encourage the discovery and production in Florida of vaccines that prevent disease.

(i) The center shall monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research. If the center determines that there is a need for increased donation of human tissue, it shall notify hospitals licensed pursuant to chapter 395 which have entered into partnership agreements with research institutes conducting stem cell research located in the same geographic region as the researchers demanding the stem cells or other tissues. Such hospitals shall implement programs that encourage voluntary donations of cord blood or other needed adult tissue.

(j) The center shall be funded through private, state, and federal sources.

(k) The center shall serve as a registry of all known opportunities for biomedical grants ~~and may assist any public or private biomedical research program in this state in preparing grant requests~~.

(l) The center shall provide grants for cancer research to further the search for cures for cancer.

1. Emphasis shall be given to the goals enumerated in s. 381.921, as those goals support the advancement of such cures.

2. Preference may be given to grant proposals that foster collaborations between institutions, researchers, and community practitioners, as such proposals support the advancement of cures through basic or applied research, including cancer clinical trials and related networks.

(m) ~~(l)~~ The center shall maintain a website with links to peer-reviewed biomedical research. The website shall also contain a list of all known biomedical research being conducted in Florida and shall facilitate communication among researchers and other interested parties.

(n) ~~(m)~~ The center shall submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in this state.

(5) There is established within the center an advisory council that shall meet at least annually.

(a) The council shall consist of one representative from a Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more than $10 million in annual grant funding from the National Institutes of Health, to be appointed by the Secretary of Health from a different institution each term, and ~~the members of the board of directors of the Florida Research Consortium and at least~~ one representative from and appointed by each of the following entities:

1. The Emerging Technology Commission.
2. Enterprise Florida, Inc.
3. BioFlorida.
4. The Biomedical Research Advisory Council.
5. The Florida Medical Foundation.
6. Pharmaceutical Research and Manufacturers of America.
7. The Florida Tri-Agency Coalition on Smoking OR Health.

8. The Florida Cancer Council.

9. The American Cancer Society, Florida Division, Inc.

10. The American Heart Association.

11. The American Lung Association of Florida.

12. The American Diabetes Association, South Coastal Region.

13. The Alzheimer's Association.

14. The Epilepsy Foundation.

15. The National Parkinson Foundation.

16. The Florida Public Health Foundation, Inc.

17. The Florida Research Consortium ~~Scripps Florida or the entity formed in this state by The Scripps Research Institute~~.

(b) Members of the council shall serve without compensation, and each organization represented shall cover all expenses of its representative.

(6) Members shall be appointed to 4-year terms of office. The members of the advisory council shall annually elect a chair from among the members of the advisory council. Any vacancy on the advisory council shall be filled in the same manner as the original appointment.

(7) The advisory council shall meet at least annually, but may meet as often as it deems necessary to carry out its duties and responsibilities. The advisory council may take official action by a majority vote of the members present at any meeting at which a quorum is present.

(8)(a) Applications for cancer research funding may be submitted from any university or established research institute in the state. All qualified investigators in the state,

regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Collaborative proposals, including those that advance the center's goals enumerated in paragraph (3)(l), may be given preference. Grants shall be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

3. Collaborative research grants, including those that advance the finding of cures through basic or applied research.

(b) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the Secretary of Health, in consultation with the council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

(c) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a

member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(9) The Legislature may annually appropriate funds to the Florida Center for Universal Research to Eradicate Disease for research grants and for operating costs.

Section 5. All appointments to the advisory council for the Florida Center for Universal Research to Eradicate Disease that were not made in accordance with s. 381.855, Florida Statutes, as amended by this act, shall expire June 30, 2006, but such appointees may continue to serve until their successors are appointed. This section shall take effect upon this act becoming a law.

Section 6. Subsection (1) of section 381.921, Florida Statutes, is amended to read:

381.921 Florida Cancer Council mission and duties.--The council, which shall work in concert with the Florida Center for Universal Research to Eradicate Disease to ensure that the goals of the center are advanced, shall endeavor to dramatically improve cancer research and treatment in this state through:

(1) Efforts to significantly expand cancer research capacity in the state by:

(a) Identifying ways to attract new research talent and attendant national grant-producing researchers to ~~Florida-based~~ cancer research facilities in this state;

(b) Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;

(c) Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;

(d) Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;

(e) Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and

(f) Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.

Section 7. Section 381.922, Florida Statutes, is created to read:

381.922 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.--

(1) The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, which may be otherwise cited as the "Bankhead-Coley Program," is created within the Department of Health. The purpose of the program shall be to advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process pursuant to s. 381.855.

(2) By December 15 of each year, the Department of Health shall submit to the Governor, the President of the Senate, and

the Speaker of the House of Representatives a report indicating progress towards the program's mission and making recommendations that further its purpose.

Section 8. Subsection (1) of section 561.121, Florida Statutes, is amended to read:

561.121 Deposit of revenue.--

(1) All state funds collected pursuant to ss. 563.05, 564.06, and 565.12 shall be paid into the State Treasury and disbursed in the following manner:

(a)~~1.~~ Two percent of monthly collections of the excise taxes on alcoholic beverages established in ss. 563.05, 564.06, and 565.12 shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund to meet the division's appropriation for the state fiscal year.

~~2. Beginning July 1, 2004, there is annually distributed $15 million to the Grants and Donations Trust Fund within the Department of Elderly Affairs, and these funds are annually appropriated to support a contract with the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for the purposes of conducting research, developing and operating integrated data projects, and providing assistance to memory disorder clinics as established in s. 430.502.~~

~~3. Beginning July 1, 2004, there is annually distributed $6 million to the Biomedical Research Trust Fund within the Department of Health, and these funds are annually appropriated to the James and Esther King Biomedical Research Program. From these funds, up to $250,000 shall be available annually for the~~

~~operating costs of the Florida Center for Universal Research to Eradicate Disease.~~

~~4. Beginning July 1, 2004, there is annually distributed $9 million to be paid by warrant drawn by the Chief Financial Officer upon the State Treasury to Florida State University for the School of Chiropractic Medicine. Notwithstanding the provisions of chapter 216, until the School of Chiropractic Medicine is completely staffed and fully operational, these funds may be used for any purpose by the university.~~

(b) The remainder of the funds collected pursuant to ss. 563.05, 564.06, and 565.12 ~~collection~~ shall be credited to the General Revenue Fund.

Section 9. Subsections (2) and (6) of section 1004.445, Florida Statutes, are amended, present subsections (8), (9), and (10) are renumbered as subsections (9), (10), and (11), respectively, and new subsections (8) and (12) are added to that section, to read:

1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.--

(2)(a) The State Board of Education shall enter into an agreement for the utilization of the facilities on the campus of the University of South Florida to be known as the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, including all furnishings, equipment, and other chattels used in the operation of those facilities, with a Florida not-for-profit corporation organized solely for the purpose of governing and operating the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute. This not-for-profit corporation, acting as

an instrumentality of the state, shall govern and operate the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute in accordance with the terms of the agreement between the State Board of Education and the not-for-profit corporation. The not-for-profit corporation may, with the prior approval of the State Board of Education, create either for-profit or not-for-profit corporate subsidiaries, or both, to fulfill its mission. The not-for-profit corporation and its subsidiaries are authorized to receive, hold, invest, and administer property and any moneys acquired from private, local, state, and federal sources, as well as technical and professional income generated or derived from practice activities of the institute, for the benefit of the institute and the fulfillment of its mission.

(b) ~~1.~~ The affairs of the not-for-profit corporation shall be managed by a board of directors who shall serve without compensation. The board of directors shall consist of the President of the University of South Florida and the chair of the State Board of Education, or their designees, five ~~5~~ representatives of the state universities, and nine ~~no fewer than 9 nor more than 14~~ representatives of the public who are neither medical doctors nor state employees. Each director who is a representative of a state university or of the public shall be appointed to serve a term of 3 years. The chair of the board of directors shall be selected by a majority vote of the directors. Each director shall have only one vote.

~~2. The initial board of directors shall consist of the President of the University of South Florida and the chair of the State Board of Education, or their designees; the~~ Of the

five university representatives, ~~of whom~~ one shall be appointed by the Governor, two by the President of the Senate, and two by the Speaker of the House of Representatives; and of the nine public representatives, ~~of whom~~ three shall be appointed by the Governor, three by the President of the Senate, and three by the Speaker of the House of Representatives. ~~Upon the expiration of the terms of the initial appointed directors, all directors subject to 3-year terms of office under this paragraph shall be appointed by a majority vote of the directors and the board may be expanded to include additional public representative directors up to the maximum number allowed.~~ Any vacancy in office shall be filled in the same manner as the original appointment ~~for the remainder of the term by majority vote of the directors~~. Any director may be reappointed.

(6) The institute shall be administered by a chief executive officer, who shall be appointed by and serve at the pleasure of the board of directors of the not-for-profit corporation, and who shall exercise the following powers and duties, subject to the approval of the board of directors:

(a) The chief executive officer shall establish programs that fulfill the mission of the institute in research, education, treatment, prevention, and early detection of Alzheimer's disease; however, the chief executive officer may not establish academic programs for which academic credit is awarded and which culminate in the conferring of a degree, without prior approval of the State Board of Education.

(b) The chief executive officer shall have control over the budget and the moneys appropriated or donated to the

institute from private, local, state, and federal sources, as well as technical and professional income generated or derived from practice activities of the institute. However, professional income generated by university faculty from practice activities at the institute shall be shared between the institute and the university as determined by the chief executive officer and the appropriate university dean or vice president.

(c) The chief executive officer shall appoint representatives of the institute to carry out the research, patient care, and educational activities of the institute and establish the compensation, benefits, and terms of service of such representatives. Representatives of the institute shall be eligible to hold concurrent appointments at affiliated academic institutions. University faculty shall be eligible to hold concurrent appointments at the institute.

(d) The chief executive officer shall have control over the use and assignment of space and equipment within the facilities.

(e) The chief executive officer shall have the power to create the administrative structure necessary to carry out the mission of the institute.

(f) The chief executive officer shall have a reporting relationship to the Commissioner of Education.

(g) The chief executive officer shall provide a copy of the institute's annual report to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education. The annual report shall describe the expenditure of all funds

and shall provide information regarding research that has been conducted or funded by the center, as well as the expected and actual results of such research.

(h) By August 1 of each year, the chief executive officer shall develop and submit to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education an annual operating budget detailing the planned use of state, federal, and private funds for the fiscal year.

(8)(a) Applications for Alzheimer's disease research funding may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Grants shall be awarded by the board of directors of the not-for-profit corporation, after consultation with the CURED advisory council created under s. 381.855, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

(b) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the board of directors of the not-for-profit corporation, in consultation with the council of scientific advisors, shall appoint a peer review panel of independent, scientifically

qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

(c) The council of scientific advisors and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest and confidentiality which shall comply with National Institutes of Health standards. All employees, members of the board of directors, and affiliates of the not-for-profit corporation shall follow the same rigorous guidelines for ethical conduct and shall adhere to the same strict policy with regard to conflict of interest and confidentiality. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(12) The Legislature may annually appropriate funds to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for the purposes of this section.

Section 10. All appointments to the board of directors of the not-for-profit corporation for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute that were not made in

accordance with s. 1004.445, Florida Statutes, as amended by this act, shall expire June 30, 2006, but such appointees may continue to serve until their successors are appointed. This section shall take effect upon this act becoming a law.

Section 11. (1) The sum of $6 million is appropriated from the General Revenue Fund to the Biomedical Research Trust Fund in the Department of Health for fiscal year 2006-2007 for purposes of the James and Esther King Biomedical Research Program pursuant to s. 215.5602, Florida Statutes.

(2) The sum of $9 million is appropriated from the General Revenue Fund to the Florida Center for Universal Research to Eradicate Disease within the Department of Health for fiscal year 2006-2007 to be distributed pursuant to s. 381.855, Florida Statutes, to provide grants to researchers seeking cures for cancer, with emphasis given to the goals enumerated in s. 381.921, Florida Statutes.

(3) The sum of $15 million is appropriated from the General Revenue Fund to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for fiscal year 2006-2007 for the purposes of conducting research, developing and operating integrated data projects, and providing assistance to memory disorder clinics as provided under s. 430.502, Florida Statutes. Not less than 80 percent of these funds shall be distributed by the center as institutional research grants or investigator-initiated research grants.

Section 12. Except as otherwise expressly provided in this act and except for this section, which shall take effect upon

this act becoming a law, this act shall take effect July 1, 2006.

Workshop
HB 645

A bill to be entitled

An act relating to nursing home facilities; creating s. 400.0627, F.S.; providing legislative intent; requiring the Agency for Health Care Administration to reimburse nursing home facilities for the cost of building or modifying their emergency electrical power systems to fully operate during and after an emergency; providing eligibility criteria for reimbursement; providing an appropriation; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 400.0627, Florida Statutes, is created to read:

400.0627 Emergency electrical power system capacity.--

(1) It is the intent of the Legislature that each nursing home facility in this state be encouraged to have an emergency electrical power system capacity that is sufficient to remain fully operational during and after an emergency in order to maintain the safety and health of the residents of the nursing home facility and, if necessary, to provide care to residents evacuated from other nursing home facilities.

(2) The agency shall reimburse an eligible nursing home facility for the costs of building or modifying its emergency electrical power system capacity to fully operate the facility during and after an emergency. To be eligible for reimbursement, a nursing home facility must:

(a) Not have been cited for any class I deficiency within

the 30 months preceding the application for reimbursement;

(b) Not be located within the hurricane evacuation zone of the county in which it is located;

(c) Have the capacity, as determined by the agency, to care for residents evacuated from other nursing home facilities during an emergency; and

(d) Agree to receive residents who are transferred from other nursing home facilities.

(3) This section does not require a nursing home facility to modify its existing emergency electrical power system capacity.

Section 2. The sum of $ is appropriated from the General Revenue Fund to the Agency for Health Care Administration for the purpose of reimbursing eligible nursing home facilities for the costs of building or modifying their emergency electrical power system capacity to fully operate the facility during and after an emergency during the 2006-2007 fiscal year.

Section 3. This act shall take effect upon becoming a law.

oppaga

Inflated Pricing & Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

A Presentation to the House Health Care General Committee

March 8, 2006

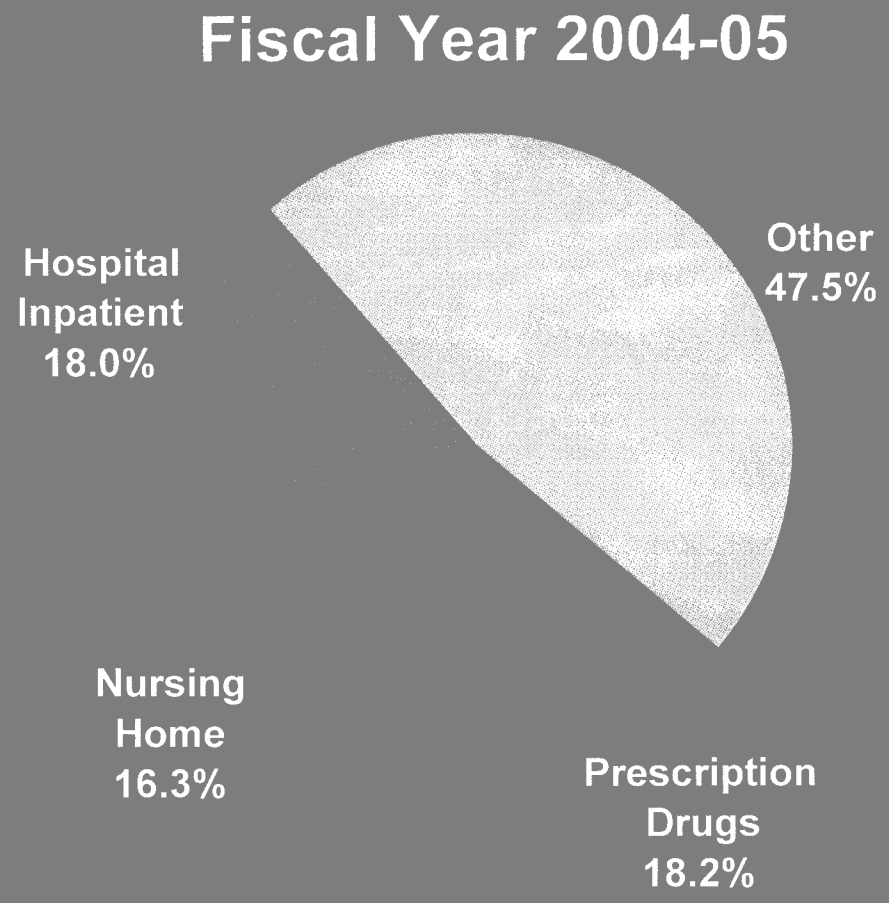
Jennifer Johnson, Senior Legislative Analyst

Florida Legislature Office of Program Policy Analysis & Government Accountability

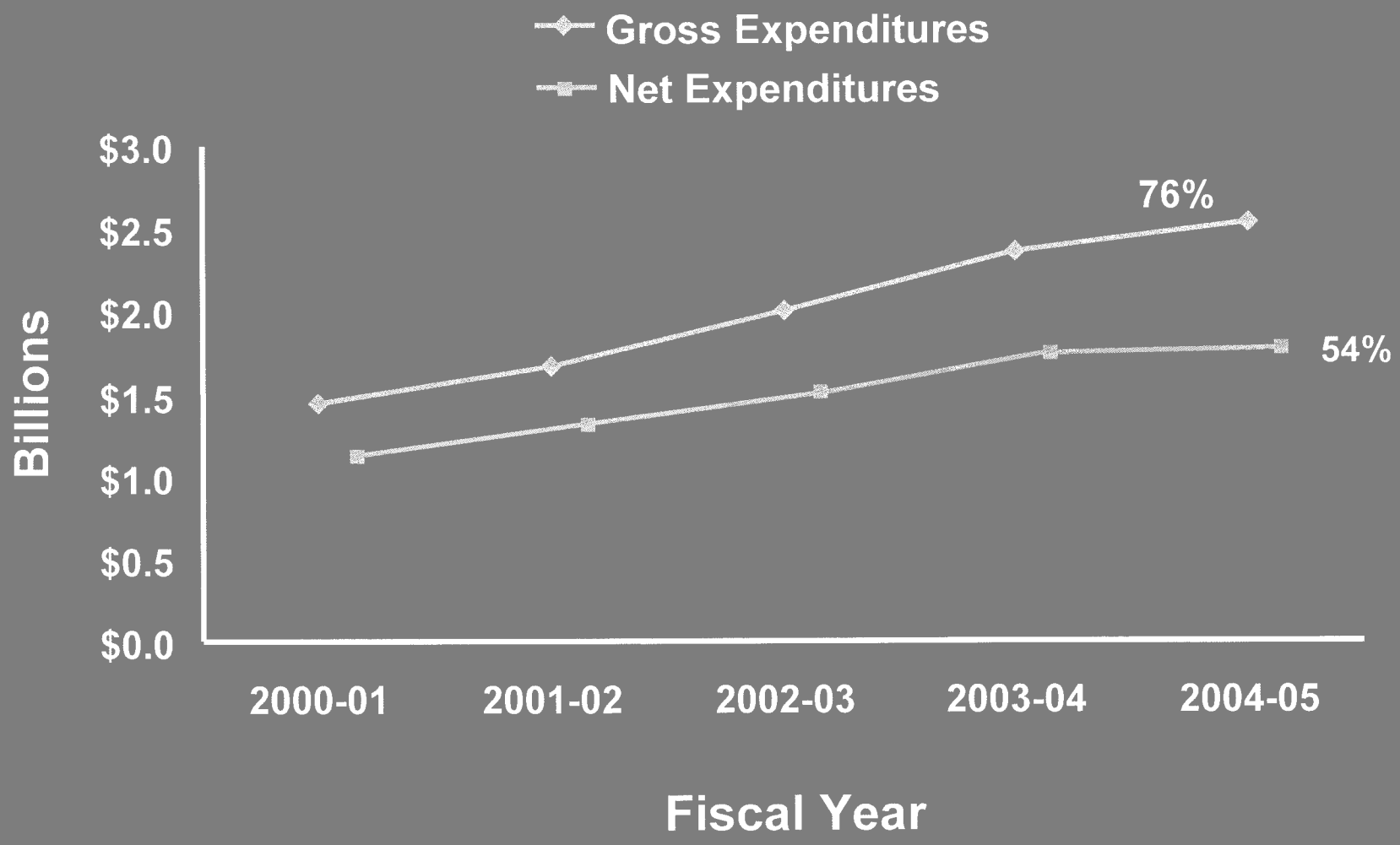
Presentation Overview

- Medicaid drug expenditures
- Medicaid drug pricing in Florida
- Flaws in Medicaid pricing
- Recommendations

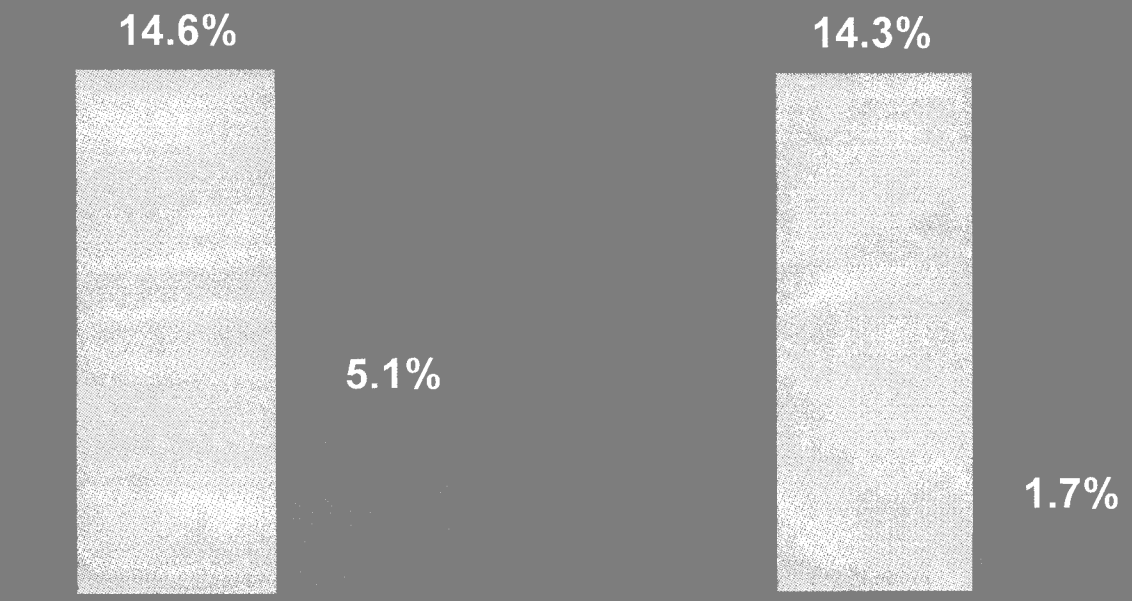
Prescription Drugs Accounted for 18.2% of Medicaid Spending



Medicaid Drug Expenditures



Average Prescription Cost Increased at a Slower Rate



Florida Medicaid Drug Prices

- Pharmacy reimbursements
- Federal and state supplemental rebates

Pharmacy Reimbursements

Federal guidelines direct states to reimburse pharmacies the lower of the:

- *Estimated acquisition cost* plus dispensing fee, or
- Usual and customary price

Estimated Acquisition Cost

AHCA determines *estimated acquisition costs* by calculating and selecting the lowest of the following:

- Average Wholesale Price (AWP) - 15.4%
- Wholesale Acquisition Cost (WAC) + 5.75%
- The Federal Upper Limit (FUL)
- The State Maximum Allowable Cost (SMAC)

Rebates

- **Federal rebates**
  - Brand name drugs
    - 15.1% of Average Manufacturer Price (AMP) or the difference between the AMP and best price
    - Additional rebate based on inflation
  - Generic drugs
    - 11 % of Average Manufacturer Price (AMP)
- **State supplemental rebates**
  - At least 14% of AMP unless federal or state rebate, or both, equal or exceed 29% of AMP

Fundamental Flaws with Medicaid Pricing

- **Federal research reports:**
  - AWP and WAC are often significantly higher than the prices pharmacies actually pay
- **U.S. Department of Justice and state attorney general investigations reveal intentional inflation by some manufacturers**

Fundamental Flaws (cont.)

This is particularly problematic with the generic drug market

$95.30	$14.00	$14.98	None	$4.36	$10.62	244%
$74.90	$9.31	$9.96	$27.60	$4.49	$5.47	122%
$2,687	$712.50	$2,330.97	$683.00	$97.88	$585.12	598%

Fundamental Flaws (cont.)

- Average Manufacturer Price is a better benchmark for estimating acquisition costs
- However, it is confidential and most states do not have access to it

Recommendations

- Require manufacturers to submit AMP and 'Net Wholesaler Price' and direct AHCA to use information to reimburse pharmacies
  - Federal legislation passed by Congress will allow states access to AMP for Medicaid pricing
  - Texas requires manufacturers to submit AMP and 'net wholesaler prices'

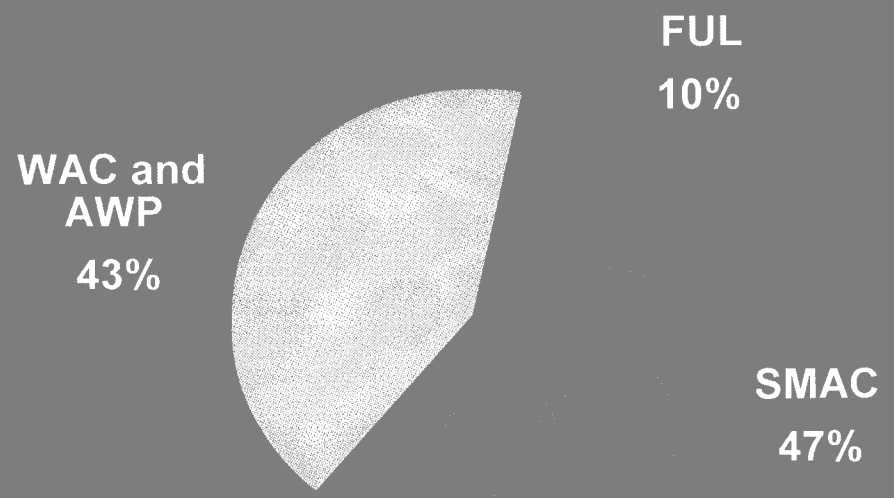
Recommendations

Modify formulas for estimating pharmacy acquisition costs

Drug	AWP-17%	$ 4.6 million
Generics[1]	AWP-40%	20.0 million
Total		$24.6 million

Recommendations

Expand state maximum allowable costs for generic drugs and update more frequently



In the fourth quarter of FY 2004-05, the SMAC price was the lowest price for only 47% of drugs with a SMAC price

Recommendations

- Negotiate supplemental rebates for generic drugs
  - Adjust dispensing fee to encourage pharmacies to dispense generic drugs that receive rebates
- Evaluate joining a purchasing pool
  - Medicare Part D may affect ability to negotiate supplemental rebates

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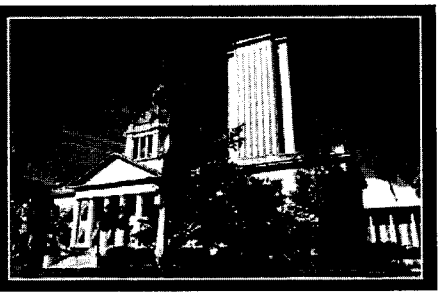


January 2006 Report No. 06-07

Inflated Pricing and Confidential Information Prevent Medicaid from Ensuring Lowest Prescription Drug Prices

at a glance

Medicaid prescription drug expenditures, which were $2.5 billion in Fiscal Year 2004-05, have nearly doubled since Fiscal Year 2000-01, growing an average of 15.1% per year. Legislative actions have helped to slow the growth rate of these expenditures, which rose at an average rate of 21.2% annually during the previous five-year period (Fiscal Years 1995-96 to 1999-00). Much of this slowed growth has been the result of specific cost-containment actions directed at lowering the price that Medicaid pays for drugs.

However, the state's ability to obtain the lowest possible prices for prescription drugs is hindered by inflated manufacturer pricing information and lack of access to confidential information. The Legislature should consider requiring pharmaceutical manufacturers to submit more accurate pricing information to the Agency for Health Care Administration (AHCA) as well as requiring AHCA to strengthen cost-containment strategies to achieve lower prescription drug prices.

Scope

As required by Chapter 2005-133, *Laws of Florida,* this report discusses Medicaid prescription drug pricing, issues that contribute to inflated prescription drug prices, and options for obtaining savings in Medicaid's prescription drug program by paying prices that are closer to pharmacy costs.

Background

Florida's Medicaid program, administered by the Agency for Health Care Administration (AHCA), is among the largest in the country, serving approximately 2.3 million persons each month. Medicaid provides health care coverage to low-income persons who meet federal and state eligibility requirements, including low-income families and children, elderly persons who need long-term care services, and persons with disabilities.

For Fiscal Year 2005-06, the Legislature appropriated $15.6 billion, including nearly $4.5 billion in general revenue, to operate the Medicaid program.[1] Most of these funds ($15.4 billion) will pay for health care services for Medicaid recipients, while $225 million (1.4%) will pay for administrative functions such as program planning, data processing, and contract management.

Florida provides prescription drug coverage as part of its Medicaid program.[2] For outpatient services, Medicaid pays for most prescription drugs and selected over-the-counter medicines.[3]

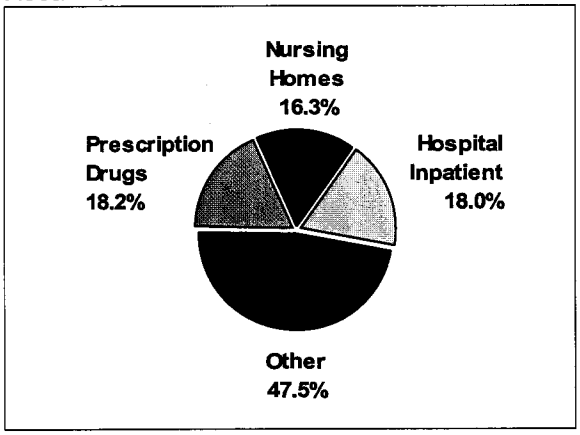
[1] The remaining $11.1 billion comes from trust funds that include federal matching funds as well as other state funds from hospital taxes, drug rebates, and county contributions.

[2] The prescription drug program is an optional Medicaid service, but all states provide prescription drug coverage.

[3] Medicaid does not make specific prescription drug payments to health maintenance organizations and hospitals as prescription drug costs are included as part of their reimbursement.

In Fiscal Year 2004-05, the Florida Medicaid program paid $2.5 billion for prescription drugs. As shown in Exhibit 1, this represented 18.2% of the expenditures for all Medicaid services that year.

Exhibit 1
Prescription Drugs Accounted for 18.2% of Total Expenditures for Medicaid Services in Fiscal Year 2004-05



Source: OPPAGA analysis of AHCA expenditure data.

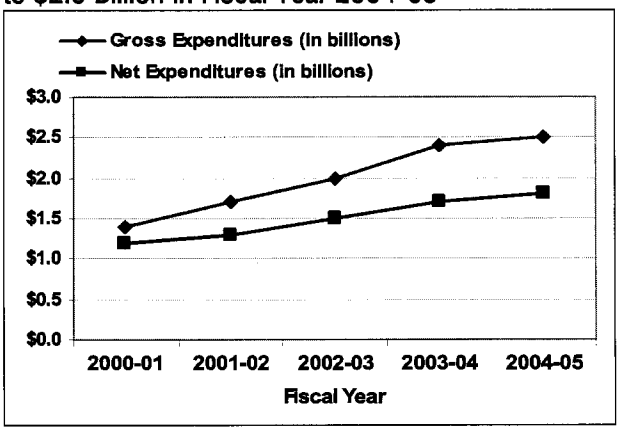
Findings

Prescription drug expenditures have continued to increase, but legislative actions have slowed the growth of these expenditures

Prescription drug expenditures have been one of the fastest growing components of health care and continue to increase annually. To address this rapid growth in the Medicaid program, the Legislature has directed AHCA to implement several cost-containment strategies to slow increases in the price of prescription drugs. These strategies have been successful in slowing both the rate of growth in drug expenditures and the average price per prescription.

Exhibit 2 shows that Medicaid gross prescription drug expenditures increased from around $1.4 billion in Fiscal Year 2000-01 to $2.5 billion in Fiscal Year 2004-05 (or 76%). [4] This represents an average annual growth rate of 15.1% compared to 21.2% annually during the prior five-year period (Fiscal Year 1995-96 to Fiscal Year 1999-00).

Exhibit 2
Medicaid Gross Prescription Drug Expenditures Increased from $1.4 Billion in Fiscal Year 2000-01 to $2.5 Billion in Fiscal Year 2004-05



Source: OPPAGA analysis of AHCA expenditure data.

Net drug expenditures, which take into account federal and state rebates, grew by 54% between Fiscal Year 2000-01 and Fiscal Year 2004-05. (See Exhibit 2.) The annual growth rate during this period was 11.4% which is substantially lower than the 20.9% average net cost increase experienced between Fiscal Years 1995-96 to 1999-00.

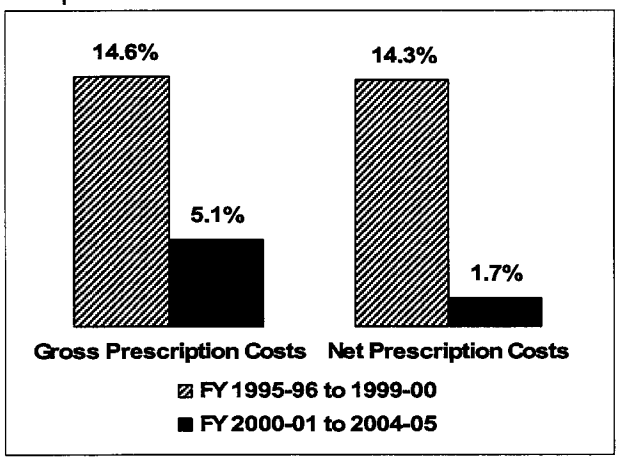
This slower rate of expenditure growth likely resulted from legislatively mandated strategies to control drug price increases. In recent years, the Legislature has mandated that AHCA implement a preferred drug list, which shifts utilization to lower cost drugs and requires brand name drug manufacturers to pay additional cash rebates to the state. The Legislature also has directed AHCA to adjust its pharmacy reimbursement formulas to yield greater discounts and to establish state maximum prices for generic drugs.

The slowed growth in the average price per prescription over the last five years demonstrates the overall success of these strategies. The average price per prescription, without considering rebates, grew by 5.1% during the past five years compared to 14.6% for

[4] Gross expenditures represent total reimbursements to providers and do not account for federal and state rebates. Both Fiscal Year 2004-05 gross and net pharmacy expenditures may change as providers submit final invoices and the state reconciles federal and state rebates.

the previous five-year period. Due to savings achieved from federal and state supplemental rebates, the net cost per prescription grew at a much slower average rate (1.7%) over the past five years compared to the previous five-year period (14.3%). (See Exhibit 3.)

Exhibit 3
Average Prescription Costs Grew at a Slower Rate Between Fiscal Years 2000-01 and 2004-05 Compared to the Prior Five Years



Source: OPPAGA analysis of AHCA drug expenditure data.

Appendix A summarizes Florida's strategies to control Medicaid prescription drug costs and how they have slowed the rate of price increases.

Fundamental flaws related to manufacturer pricing information prevent the state from ensuring that it pays the lowest possible price for prescription drugs

Florida, like all states, seeks to obtain the lowest possible prices for Medicaid prescription drugs. [5] Pricing for prescription drugs is highly complex and is based on the prices paid to pharmacies as well as manufacturer rebates that are required by the federal and some state governments. However, Florida's ability to ensure that it is paying the lowest possible cost for Medicaid prescription drugs is hindered because it must establish pharmacy reimbursement rates using manufacturers' published prices that are inflated and unreliable. While the federal government collects data on manufacturer prices based on actual sales transactions, this information is confidential. As a result, Florida's Medicaid program can not be certain that it obtains the lowest possible prices for prescription drugs.

Pharmacy reimbursements and manufacturer rebates determine how much Florida's Medicaid program pays for prescription drugs. The amount that Florida's Medicaid program spends for prescription drugs depends on two factors: (1) how much Medicaid pays pharmacies for these drugs, and (2) how much Medicaid receives from drug manufacturers in cash rebates. Each state's Medicaid program determines, within federal guidelines, what to pay pharmacies for dispensed drugs. In addition, all states receive manufacturer rebates that are prescribed by federal law, and some states, including Florida, also negotiate with manufacturers for additional rebates (state supplemental rebates). Florida's gross expenditures for Medicaid drugs are reduced by the amount of these manufacturer rebates. In Fiscal Year 2004-05, Florida received $735 million in federal and state manufacturer rebates. [6]

Florida's Medicaid program pays pharmacies the lower of two costs: (1) what it estimates pharmacies pay for drugs (referred to as acquisition costs) plus a $4.23 dispensing fee, or (2) the pharmacy's usual and customary price for the drug. [7] As illustrated in Exhibit 4, AHCA's prescription drug pricing algorithm first selects the lowest estimated acquisition cost and adds the dispensing fee. The algorithm then compares this price to the pharmacy's usual and customary price and pays the lower of these prices. AHCA estimates acquisition costs using two nationally published prices, the Average Wholesale Price (AWP) and the Wholesale Acquisition Cost (WAC); and two maximum prices, the federal upper limit (FUL) and the state maximum

[5] Federal legislation intends for the Department of Veteran's Affairs, the Department of Defense, the Public Health Service, and the U.S. Coast Guard to receive the lowest prices for prescription drug purchases.

[6] Final rebates for Fiscal Year 2004-05 could change as rebates are received and reconciled.

[7] The usual and customary charge reflects the prescription price for persons without insurance.

allowable cost (SMAC).[8] Appendix B provides a glossary of prescription drug pricing terms, and Appendix C details the agency's methods for estimating pharmacy acquisition costs. Appendix D describes the federal and state rebate processes.

Exhibit 4
AHCA Reimburses Pharmacies by Paying the Lower of AHCA's Estimated Prescription Cost or the Usual and Customary Price

STEP 1 Identify published and maximum prices	Published AWP = $1.25 Published WAC = $1.00 FUL = $0.98 SMAC = $0.97	
STEP 2 Calculate estimated pharmacy acquisition costs and select lowest price	AWP - 15.4% = $1.0575 [1] WAC+ 5.75% = $1.0575 FUL = $0.98 SMAC = $0.97 (select)	
STEP 3 Add the dispensing fee and estimate the prescription cost for 30 pills	$29.10 Drug costs ($0.97 X 30) + 4.23 Dispensing fee $33.33 Estimated prescription cost	
STEP 4 Compare estimated prescription cost to the usual and customary (U&C) price and select the lower price to reimburse the pharmacy	Estimated cost = $33.33 U&C = $35.00 Pay pharmacy = $33.33	

Definitions

- Average Wholesale Price (**AWP**). Retail list price (sticker price) or the average price manufacturers recommend that wholesalers sell to physicians, pharmacies, and others.
- Wholesale Acquisition Cost (**WAC**). The average cost at which a manufacturer sells a drug to wholesalers.
- Federal Upper Limit (**FUL**). The maximum amount that the federal government establishes for selected multi-source generic drugs.
- State Maximum Allowable Cost (**SMAC**). The maximum amount a particular state establishes for payment of selected multi-source generic drugs; these can be lower than FUL prices.

[1] Because AWP prices are generally 25% over WAC prices, the state's pricing formulas create equivalent AWP and WAC price estimates.

Source: OPPAGA.

Both federal law and Florida law require manufacturers to provide cash rebates in order for Medicaid to cover their products. These rebates must reach a minimum percentage of the average manufacturer price (AMP).[9] The AMP reflects the average price at which manufacturers sell their products, after accounting for purchasers' discounts and rebates. The Centers for Medicare and Medicaid Services (CMS) calculates federal rebates using AMP information, which manufacturers report quarterly to CMS. Florida statute also requires AHCA to establish state supplemental rebates for brand name drugs based on a minimum percentage of the AMP.

Unreliable information, inflated prices, and confidential manufacturer prices prevent Medicaid from ensuring that it pays the lowest price. To estimate the price that pharmacies pay for drugs, Florida, as most states, generally uses published prices (AWP and WAC) provided by manufacturers that are reported in commercial publications.[10] However, pharmacies' actual purchase prices are sometimes significantly lower than these published prices. Research conducted by the Congressional Budget Office and the U.S. Department of Health and Human Services' Office of the Inspector General suggests that pharmacies sometimes purchase drugs at prices significantly lower than published prices. Since states set pharmacy reimbursements by estimating acquisition costs using published prices, states could sometimes reimburse pharmacies at rates that are high relative to pharmacy costs.

Recently settled federal and state lawsuits have shown that some manufacturers have intentionally inflated the AWP and WAC prices reported to companies that publish manufacturer prices. For example, in September 2005, the United States Department of Justice settled with one manufacturer for $150 million for fraudulent and inflated pricing of two drugs. Florida's Attorney General has subpoenaed six manufacturers for reporting inflated AWP and WAC prices. The results of these suits are pending but could represent over $100 million in

[8] AHCA obtains manufacturer prices from First DataBank, a supplier of electronic drug information that publishes AWP and WAC prices, which represent manufacturers' published list prices to wholesalers and pharmacies.

[9] Federal rule stipulates that manufactures pay rebates at a minimum of 15.1% of the AMP for brand name drugs and 11% for generic drugs. State law requires that total federal and state rebates for brand name drugs reach a minimum of 29% of the AMP. Florida does not negotiate generic rebates.

[10] In addition to *First DataBank*, other industry publications include the *Red Book*, the *Blue Book*, and *Medi-Span*.

overpayments plus additional fines. In addition, at least 16 states besides Florida have filed lawsuits against manufacturers for inflated pricing practices. [11]

Manufacturers that inflate AWP and WAC published prices do so to encourage pharmacies to purchase their products. By selling drugs to pharmacies at much lower prices, manufacturers achieve higher sales volume and pharmacies achieve a greater profit margin. However, this occurs at the expense of the Medicaid program which pays more than it should for prescription drugs. For example, in an April 2005 Florida lawsuit, the Attorney General's Office charged one manufacturer with reporting prices nearly 600% higher than a pharmacy's actual cost to purchase the drug. One instance cited in this lawsuit showed that Florida's Medicaid program reimbursed a pharmacy based on an inflated AWP published price, resulting in the state paying $683 for a drug that only cost the pharmacy $97.88. While such price inflation can occur in both brand name and generic markets, the competitive nature of the generic market is much more susceptible to this practice. [12]

A more ideal benchmark for Florida to use when estimating pharmacy drug purchase costs is the Average Manufacturer Price (AMP). This price takes into account available discounts and rebates, and policy experts generally consider it to be the most accurate market price. However, manufacturers generally keep these prices confidential except to the federal government which uses them to determine rebates. Thus, states cannot use AMP information to estimate pharmacy costs unless they require such access in state law. The U.S. Congress is currently considering making AMP information available to states. If this legislation passes, states would have access to AMP information without having to require access in state law. [13]

Texas state law requires manufacturers to submit AMP information to its Medicaid program quarterly. The Texas Medicaid program retains the confidentiality of manufacturer information but uses this data to compare against the 'net wholesaler price' that Texas also requires manufacturers to report. Texas uses this 'net wholesaler price' instead of the published WAC to estimate wholesaler acquisition costs. The 'net wholesaler price' differs from the commonly published WAC as it includes all forms of manufacturer discounts. In instances when an AMP is significantly lower than the 'net wholesaler price,' the Texas Medicaid program, in conjunction with the Texas Attorney General's Office, requires the manufacturer to revise the 'net wholesaler price.' By doing this, Texas can better ensure that it reimburses pharmacies at prices that more appropriately reflect pharmacy costs.

Despite pricing flaws, Florida should continue efforts to reduce the cost of Medicaid prescription drugs

Even though current pricing information is flawed, Florida can work toward achieving even lower Medicaid prescription drug prices by modifying its formula for reimbursing both brand and generic drugs, expanding its maximum pricing for generic drugs, negotiating supplemental rebates for generic drugs, and/or forming or joining a multi-state purchasing pool to retain its negotiating leverage after Medicare Part D becomes effective.

The state could modify its formulas for estimating acquisition costs that use published AWP and WAC prices. The Legislature could reduce pharmacy reimbursements for some drugs by mandating a higher discount off the AWP, a lower markup on the WAC, and/or that AHCA develop separate formulas to estimate the acquisition costs for brand name and generic drugs. AHCA currently reimburses pharmacies

[11] These states are Alabama, Arizona, Arkansas, California, Connecticut, Illinois, Kentucky, Massachusetts, Minnesota, Mississippi, Missouri, Montana, New York, Ohio, West Virginia, and Wisconsin.

[12] Unlike brand name drugs in which only one manufacturer produces and markets, numerous manufacturers produce and market generic drugs. Thus, generic drug manufacturers must compete for market share, and therefore, are more likely to offer pharmacies deep discounts to purchase their products.

[13] This issue is expected to be voted on when Congress reconvenes at the end of January 2006.

at AWP-15.4% for both brand name and generic drugs. However, as of March 2005, other states were reimbursing pharmacies for brand name drugs using AWP discounts ranging from 5% to 17%. In addition, six states reimbursed pharmacies for generic drugs using AWP discounts ranging from 20% to 40%. [14] If Florida had reimbursed pharmacies at the high end of these ranges, Medicaid could have saved $24.6 million in Fiscal Year 2004-05. [15] (See Exhibit 5.)

Exhibit 5
Medicaid Could Have Saved $24.6 Million in Pharmacy Expenditures by Increasing the Discount Off the AWP in Fiscal Year 2004-05

Drug Type	Revised Discount Price	Approximate Savings Against Fiscal Year 2004-05 Expenditures
Brand Name Drug	AWP-17%	$ 4.6 million
Generics[1]	AWP-40%	20.0 million
Total		**$24.6 million**

[1]These estimates were developed only for those drugs in which the 'lowest price' would have been derived by using AWP-17% for brand named drugs and AWP-40% for generics.

Source: OPPAGA analysis using AHCA drug expenditure data.

Increasing the discount off the AWP to 17% and 40% for brand and generic drugs, respectively, would enable AHCA to reimburse pharmacies at a price that is closer to what they actually pay to purchase drugs while still allowing pharmacies to make a profit. [16] Florida could set even more aggressive discounts for estimating acquisition costs. Recent research conducted by the U.S. Department of Health and Human Services stated that manufacturer prices are on average equal to AWP-23% and AWP-70% for brand name drugs and generics, respectively. [17]

The agency should continue to expand state maximum pricing for generic drugs and update these prices more frequently. Florida sets state maximum allowable costs (SMAC) for some generic drugs that meet specific criteria, and these SMAC prices should be lower than federal upper limit prices and estimated acquisition costs using published prices. [18] As directed by the Legislature, AHCA has increased efforts to set SMAC prices for generic drugs. In the last quarter of Fiscal Year 2004-05, the SMAC price was the lowest price for 17% more generic products compared to the first quarter of that fiscal year. [19] AHCA updates SMAC prices quarterly and, between June and December 2005, nearly doubled the number of products with maximum prices. [20]

Because the generic drug market operates like a commodities market, maximum prices should be updated often. According to an industry source, generic drug prices can change frequently, with up to 25% of the prices changing weekly mainly due to competition for market share. As shown in Exhibit 6, in the last quarter of Fiscal Year 2004-05, the state maximum price was not the lowest price for over half (53%) of these products, indicating that Florida may benefit from changing SMAC prices more often than quarterly.

[14] One additional state, Washington, reimburses generics produced by five or more manufacturers at AWP minus 50%.

[15] This analysis does not estimate savings for Fiscal Year 2005-06, because implementation of the Medicare Part D Prescription Drug Plan will significantly change Medicaid drug expenditures.

[16] An equivalent adjustment also could be made to the WAC price by reducing its markup from the current 5.75%.

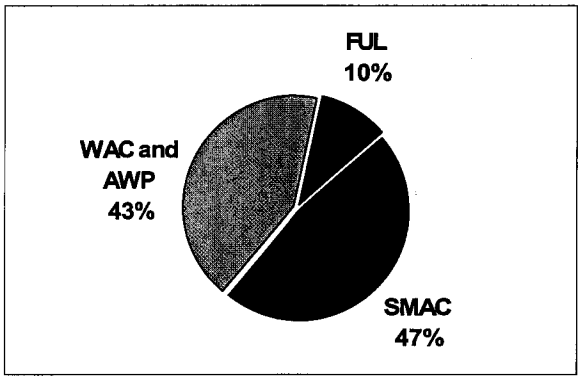
[17] *Medicaid Drug Price Comparisons: Average Manufacturer Price to Published Prices,* June 2005, U.S. Department of Health and Human Services, Office of Inspector General.

[18] The specific criteria are related to the number of manufacturers that produce the generic drug. Unlike the federal government, states are not limited to a percentage of published prices when setting maximum prices.

[19] As directed by the 2004 Legislature, AHCA expanded the SMAC program during the last quarter of the fiscal year after contracting with Provider Synergies in October 2004. Prior to contracting with Provider Synergies, AHCA set maximum prices on an ad hoc basis.

[20] The number of products refers to the total number of unique drug formulations based on characteristics such as forms (capsules, pills, liquids, etc.), dosages (50 mg, 100 mg, etc.), manufacturer, and package size.

Exhibit 6
The SMAC Price Was the Lowest Price for Only 47% of Drugs With SMAC Prices During the Last Quarter of Fiscal Year 2004-05



Source: OPPAGA analysis using AHCA drug expenditure data.

Michigan contracts with a vendor for daily price surveillance. By doing so, it has established maximum prices on two and one-half times as many drug products as Florida and changes maximum prices to follow market fluctuations. These efforts saved Michigan's Medicaid program an estimated $47 million in the first year of the contract with the vendor.

The agency could negotiate generic drug supplemental rebates. In addition to setting maximum prices for generic drugs, AHCA could negotiate supplemental rebates for generic drugs. The Legislature has authorized AHCA to negotiate generic rebates, but it has not done so. [21] In contrast, Texas has negotiated rebates for generic drugs since December 2004. The Texas Medicaid program increased its dispensing fee by $0.50 to encourage pharmacies to fill prescriptions with generic drugs for which Texas receives a supplemental rebate. Texas Medicaid officials estimate that every 1% shift from brand name to generic drugs generates about $15 million in savings. [22]

ACHA should evaluate forming or joining a purchasing pool to preserve negotiating power. In January 2006 with the implementation of the Medicare Part D Prescription Drug Plan, approximately 377,000 Medicaid 'dual eligibles' will transition onto the Medicare plan thereby reducing Medicaid prescription drug volume and shifting drug purchasing patterns. [23] Overall state expenditures are expected to decrease by nearly $1.2 billion representing 19.1 million prescriptions or 50% of the expenditures, with purchases in some therapeutic classes likely to decrease by up to 75%. This change in spending could reduce Florida's ability to continue negotiating the same level of supplemental rebates.

Some states have increased their negotiating power with drug manufacturers by forming multi-state purchasing pools. [24] For example, Michigan is part of a nine-state pool that contracts with a pharmacy benefit manager to manage their pool. The vendor negotiates supplemental rebates based on the total number of lives covered in the pool. Should Florida's Medicaid program lose negotiating power with supplemental rebates after implementation of Medicare Part D, AHCA should evaluate the possible benefits of joining or creating a multi-state purchasing pool.

[21] Section 409.912(39)(a)6., *F.S.* To accomplish this, the agency might need to establish an administrative structure to negotiate and invoice these rebates.

[22] While Florida Medicaid generic prescription drugs comprise only 15% of the total drug expenditures, they comprise almost 50% of total drug claims.

[23] Medicaid dual eligibles are Medicaid recipients who qualify for Medicare and Medicaid and have relied on Medicaid to pay for prescription drugs.

[24] There are currently two multi-state purchasing pools. One includes Louisiana, West Virginia, Wisconsin and Maryland. A second pool includes Michigan Alaska, Hawaii, Minnesota, Montana, Nevada, New Hampshire, Tennessee, and Kentucky.

Recommendations

To achieve lower Medicaid prescription drug prices, we recommend that the Legislature take the actions discussed below.

- **Require manufacturers to report 'net wholesaler prices' and average manufacturer prices (AMP) to AHCA and direct the agency to use this information to reimburse pharmacies.** Texas uses 'net wholesaler prices' which take into account all discounts to more accurately estimate pharmacy acquisition costs and, thereby, reduce its Medicaid prescription drug costs. Texas also uses AMP information to ensure that 'net wholesaler prices' reported by manufacturers are reasonable.
- **Direct AHCA to lower pharmacy reimbursements by modifying its formulas for estimating pharmacy acquisition costs.** AHCA currently reimburses pharmacies at AWP-15.4% for both brand name and generic drugs. Revising these formulas by increasing the discount off the AWP, reducing the markup on the WAC, and/or developing different formulas for brand name and generic drugs would estimate pharmacy costs that are closer to what pharmacies actually pay for drugs.
- **Direct AHCA to continue expanding state maximum pricing for generic drugs and update the maximum pricing list more frequently.** To improve maximum pricing efforts for generic drugs, AHCA should continue to increase the number of generic drugs for which it sets a maximum price. To ensure that a greater percentage of the maximum prices are the lowest price, AHCA should consider adjusting maximum prices more often than quarterly in order to respond to frequent price fluctuations in the generic drug market.
- **Direct AHCA to negotiate generic drug supplemental rebates.** Current Florida law authorizes the agency to negotiate generic rebates, but it has not done so. AHCA could model Texas' generic rebate program which allows pharmacies to dispense any generic drug without prior authorization, but encourages pharmacies to dispense rebated generics by increasing the dispensing fee for these drugs.
- **Direct AHCA to evaluate participation in a purchasing pool.** Under Medicare Part D, the state will reduce prescription drug purchases by nearly 50%, which may affect the state's ability to negotiate the current level of state supplemental rebates. Because of changes in volume and purchasing patterns due to Medicare Part D, AHCA should evaluate the benefits of joining or creating a multi-state purchasing pool.

Appendix A

Medicaid Pharmacy Cost-Containment Strategies Have Slowed Price Increases for Prescription Drugs

Two major factors contribute to increases in Medicaid prescription drug expenditures, price and volume. Volume takes into account utilization (or the number of prescriptions used per person), and enrollment (or the number of persons participating in the Medicaid program). Since 2000, Florida has implemented many strategies to slow growth in Medicaid prescription drug expenditures. Many of these strategies have focused specifically on controlling drug prices. For example, the Legislature required the Agency for Health Care Administration (AHCA) to take the actions described below.

- **Implement a mandatory Preferred Drug List (PDL).** The 2001 Legislature directed the agency to develop a mandatory PDL and negotiate state supplemental rebates with manufacturers. OPPAGA found that the PDL saved $81 million in its first year of implementation. [25] The PDL includes drugs by therapeutic class that are efficacious and have a low cost relative to other drugs in the class. Brand name drug manufacturers can have their drugs placed on the PDL by offering the state cash rebates, which lowers the net cost of their drugs to the state. The PDL essentially shifts utilization to lower cost drugs that are equally effective which lowers Medicaid's overall cost for prescription drugs. The Legislature has continued to strengthen the PDL, including requiring the agency to negotiate only *cash* supplemental rebates and including previously exempt mental health drugs on the preferred drug list.
- **Expand the State Maximum Allowable Cost Program (SMAC).** In Fiscal Years 2003-04 and 2004-05, the Legislature directed the agency to expand the SMAC program and reduced the agency's budget $11.8 million and $25 million, respectively, in anticipation of savings. Because pharmacies receive deep discounts from wholesalers or manufacturers of generic drugs, states set maximum prices below the price that would be paid using the standard discount off published prices. In October 2004, AHCA contracted with a private vendor to develop a more comprehensive state maximum pricing program. By the fourth quarter of Fiscal Year 2004-05, the lowest price for approximately 17% of generic drugs was the SMAC price compared to less than 1% during the first quarter of Fiscal Year 2004-05.
- **Modify formulas that estimate pharmacy acquisition costs.** In both 2000 and 2004 the Legislature directed AHCA to modify its formulas for estimating acquisition costs. The most recent modification lowered pharmacy reimbursements by (1) increasing the discount off the Average Wholesale Price (AWP) from AWP-13.25% to AWP-15.4% and (2) reducing the markup to the Wholesale Acquisition Cost (WAC) from WAC+7% to WAC + 5.75%. [26]

[25] *Progress Report: Changes to Medicaid Preferred Drug List Requirements and Competitive Bidding Pharmacy Contracts Could Save an Additional $86.6 Million in 2003-04,* Report No. 03-27, April 2003.

[26] In 2000, the Legislature directed AHCA to increase the discount off the AWP from AWP-11.5% to AWP-13.25%.

Together, these efforts have slowed the rate of price increases for Medicaid prescription drugs. An analysis of the relative contribution of price and volume shows that efforts to control prices have been effective. Table A-1 shows that over the past five years, only 15.4% of the increase in prescription drug spending was due to increases in the cost of prescriptions, while 84.6% was due to increases in volume. In contrast, during the five years prior to the Legislature taking these price control actions, 70.3% of expenditure increases were due to higher drug prices, with the remaining 29.7% due to volume.

Table A-1
Relative Contribution of Price and Volume to Drug Expenditures Has Reversed

Source of Increase	Fiscal Year 1995 -96 to Fiscal Year 1999-00	Fiscal Year 2000– 01 to Fiscal Year 2004-05
Price	70.32%	15.41%
Volume	29.68%	84.59%
Utilization	29.12%	68.91%
Enrollment	0.56%	15.68%

Source: OPPAGA analysis of AHCA pharmacy summary data.

Appendix B

Medicaid Pharmaceutical Pricing Includes Many Terms

The table below provides an alphabetical listing of terms that define the different pharmaceutical prices. The table also includes a description of how each price is used as well as the advantages, limitations, or other considerations associated with the price.

Table B-1
Pharmaceutical Pricing Terms Reflect Different Calculation Methods for Different Uses

Short Title	Pricing Term	Definition	Use	Advantages, Limitations, or Other Issues	Publicly Available
AMP	Average Manufacturer Price	The average price at which manufacturers sell drugs to wholesalers and other purchasers that distribute to pharmacies. The AMP is net of customary prompt pay discounts and rebates.	Used by the federal government to calculate rebates that drug manufacturers are required to give to state Medicaid programs	This price is defined as the average price paid to manufacturers by wholesalers for drugs distributed to retail pharmacies. This price is generally considered the most accurate market price, as it accounts for discounts and rebates.	No
ASP	Average Sales Price	The weighted average price manufacturers sell drugs to all purchasers excluding government entities. The ASP is net of all price concessions for volume, prompt pay, cash discounts, and rebates.	As of January 2005, used by the federal government to reimburse providers for drugs covered under Medicare Part B that are not covered on a cost or prospective payment basis	This price is considered to be closely aligned with the actual costs of drugs because it accounts for all discounts and rebates. However, while it is collected on a quarterly basis, there is a three- to six-month time lag.	Yes
AWP	Average Wholesale Price	Retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.	Used by states to estimate pharmacy acquisition costs.	This price is not defined in law or statute and is developed by manufacturers. This price does not accurately reflect actual market prices because it excludes discounts available to various purchasers.	Yes
Best Price	Best Price	The lowest price available from the manufacturer to any purchaser, excluding certain government purchasers.	Used by the federal government to calculate rebates that manufacturers are required to give to state Medicaid programs	This price should reflect the lowest price paid by any private-sector purchaser and must include certain discounts, such as volume discounts, that are available to purchasers.	No
EAC	Estimated Acquisition Cost	State Medicaid programs' best estimate of what a pharmacy pays for a drug.	Federal Medicaid law directs states to use an estimated acquisition cost to reimburse pharmacies.	States develop formulas that try to account for likely discounts and rebates. Research suggests that pharmacies generally receive larger discounts than those estimated, so states pay significantly more than actual pharmacy acquisition costs.	Yes

Short Title	Pricing Term	Definition	Use	Advantages, Limitations, or Other Issues	Publicly Available
FUL	Federal Upper Limit	The maximum amount that states should pay pharmacies for selected multi-source generic drugs.	Ensures that all states pay no more that the established maximum price for both the generic and brand name version of a drug.	The Centers for Medicare and Medicaid Services (CMS) sets maximum prices for generic drugs that are available from at least three manufacturers and provides this information to states. However, CMS has not set maximum prices for all eligible drugs and research suggests FUL prices are still too high.	Yes
NWAC	Net Wholesale Acquisition Cost	This is the net price that manufacturers quote to wholesalers, distributors, and direct purchasers, such as nursing homes and chain warehouses. The prices must be the net of all discounts and rebates.	The Texas Medicaid program uses this information to estimate acquisition costs.	This price is only available in Texas, as mandated by Texas state law. By requiring manufacturers to submit accurate purchaser costs, the Medicaid program can estimate acquisition costs more accurately.	Yes
SMAC	State Maximum Allowable Cost	The maximum amount a state will pay for selected multi-source generic drugs.	Ensures that the state pays no more than the state-established maximum price for both the generic and brand name version of a drug.	States set prices for selected generic drugs. Prices can be lower than the federal maximum price. Maximum price programs are difficult to develop and maintain, because generic drug prices change frequently and pharmacy purchase prices are not readily accessible.	Yes
U&C	Usual and Customary	The full retail price that individuals without insurance would pay a pharmacy for a particular drug.	Used in determining pharmacy reimbursement by comparing to the states' estimated acquisition costs and selecting the lowest price.	This price is seldom used to reimburse pharmacies for Medicaid prescription drugs as it is rarely the lowest price.	Yes
WAC	Wholesale Acquisition Cost	The average price at which a manufacturer sells a drug to wholesalers.	Used by states to estimate pharmacy acquisition costs.	This price is developed by manufacturers. It does not include prompt pay or other discounts, rebates or reductions.	Yes

Source: OPPAGA analysis of Medicaid pharmaceutical pricing terms, 2005.

Appendix C

Florida Reimburses Pharmacies the Lowest Estimated Cost

Federal Medicaid rules require states to reimburse pharmacies the lower of the estimated acquisition cost or the usual and customary cost that a pharmacy charges for a drug. [27] To estimate pharmacy acquisition costs, states use one or both of two prices reported by manufacturers to commercial companies such as First Data Bank. However, because these prices do not include the discounts and rebates that manufacturers provide to purchasers, a pharmacy's actual purchase price is lower than published prices. [28] Florida uses several approaches to estimate acquisition costs taking into account anticipated discounts.

- **Average Wholesale Price (AWP)** is the suggested or sticker price and represents the average price manufacturers suggest to wholesalers for selling prescription drugs to physicians, pharmacies, and others. Florida estimates that pharmacies purchase drugs at AWP-15.4%.
- **Wholesale Acquisition Cost (WAC)** is the reported average cost at which the manufacturer sells the drug to wholesalers. Florida estimates that pharmacies purchase drugs at WAC+5.75%
- **Federal Upper Limit (FUL)** is a maximum price set by the Centers for Medicare and Medicaid Services for some generic drugs. In general, the FUL price is 150% of the lowest price available nationally for a drug.
- **State Maximum Allowable Cost (SMAC)** is a state set maximum price for some generic drugs. Florida sets SMAC prices at the mid-range or average of several manufacturer prices.
- Florida also pays a **dispensing fee** of $4.23 for every prescription to cover pharmacy overhead costs for filling the order.

Florida compares each price estimate and pays pharmacies the lowest price plus the dispensing fee or the usual and customary price, whichever is lower.

[27] The usual and customary charge reflects the full retail price that a person without insurance would pay a pharmacy.

[28] Discounts and rebates may be awarded for prompt payment, volume purchasing, and other factors.

Appendix D

Federal and State Rebates Reduce Prescription Drug Costs

Rebates do not affect the price Medicaid pays to pharmacies but reduce state costs because manufacturers refund part of the payment price. Florida receives mandatory federal rebates and state supplemental rebates which manufacturers must pay to have their drugs included on the state's Medicaid preferred drug list. Together these rebates can substantially reduce state costs. Receiving these federal and state supplemental rebates resulted in net prescription drug expenditures for Fiscal Year 2004-05 of $1.77 billion, approximately 29.5% less than Florida's gross expenditures ($2.5 billion).

Federal rebates. The federal government requires both brand and generic drug manufacturers to provide rebates to states in order to participate in the Medicaid program. [29] Drug manufacturers report price information to the Centers for Medicare and Medicaid Services (CMS) quarterly. For each brand name drug, manufacturers report the average manufacturer price (AMP) which reflects the **average** price manufacturers receive from wholesalers **after** discounts and rebates and the Best Price, which represents the **lowest** price charged to any private purchaser **after** discounts and rebates.

For both single source and multiple source brand name drugs, manufacturers pay a basic rebate of 15.1% of the AMP or the difference between the AMP and Best Price, whichever is greater. In addition to the basic rebate, manufacturers must pay an additional rebate if the AMP price increases faster than the consumer price index for urban consumers. CMS uses a baseline AMP determined by the drug's original market date as a reference point for calculating any inflation-adjusted rebate. Because prices for many brand name drugs have increased faster than inflation, the additional rebate can be substantial. For generic drugs, manufacturers pay rebates equal to 11% of the AMP. Currently, manufacturers are not required to pay additional rebates for generic drugs based on an inflation adjustment.

Using the quarterly price information provided by manufacturers, CMS calculates and then sends states a list containing the unit rebate amount for each drug. Medicaid programs invoice each manufacturer with whom they do business. The invoice amount is determined by multiplying the number of units reimbursed by Medicaid by the unit rebate.

State supplemental rebates. The 2001 Florida Legislature directed AHCA to establish a mandatory preferred drug list (PDL) and negotiate state supplemental rebates. The PDL includes drugs by therapeutic classes that have a low cost relative to other similar drugs. Brand name drug manufacturers can get their drugs placed on the PDL by offering the state cash rebates, which lowers the net cost of the drugs to the state. The PDL essentially shifts utilization to lower cost drugs and lowers the cost of all drugs provided by the Medicaid program.

[29] The Omnibus Budget Reconciliation Act of 1990, created the federal Medicaid Drug Rebate Program, which was implemented in 1991.

To have their products considered for the PDL, manufacturers must negotiate state supplemental rebates with AHCA. According to state law, the supplemental rebate must equal no less than 14% of the AMP unless the federal or supplemental rebate, or both, equal at least 29% of the AMP. [30] AHCA contracts with Providers Synergies to negotiate a guaranteed net price for manufacturers' drugs to achieve, at a minimum, 29% of the AMP. After the state reimburses pharmacies and receives the federal rebate, manufacturers then pay the state any additional amount necessary to reach the guaranteed net price. For some drugs, the federal rebate alone almost achieves the negotiated guaranteed net price, so the state may receive a minimal supplemental rebate from manufacturers. Other times, the federal rebate is a fairly small amount compared to the negotiated price, so the supplemental rebate owed by the manufacturer will be significant.

Once AHCA and Provider Synergies negotiate the guaranteed net unit prices, the Pharmaceutical and Therapeutics Committee reviews the medical efficacy and pricing of the drugs. [31] For all drugs within a therapeutic category that are clinically similar, the committee recommends that AHCA include the lower priced drugs on the PDL. Drugs with high prices relative to peer drugs are excluded.

Since 2001, the state has expanded the PDL to cover more therapeutic classes and now requires that all supplemental rebates be cash rebates. [32] The most recent change to the PDL occurred in 2005 when the Legislature required manufacturers to negotiate supplemental rebates for mental health drugs. [33] In addition, the agency applies more stringent standards before allowing physicians to prescribe drugs that are not on the PDL.

Table D-1 shows Florida's average federal and state rebates as a percentage of Medicaid expenditures for last fiscal year. Combined these rebates reduced expenditures by 29.5%.

Table D-1
Drug Manufacturer Rebates to Florida's Medicaid Program Average 29.5% of Fiscal Year 2004-05 Prescription Drug Expenditures

Type of Drugs	Percentage Federal Rebate	Percentage State Rebate	Total Rebate
Single Source Brand Name Drugs	28.22%	5.84%	34.06%
Multiple Source Brand Name Drugs	39.51%	0.18%	39.69%
Generic Drugs	3.18%	0.13%	3.31%
All Drugs	24.56%	4.97%	29.53%

Source: Agency for Health Care Administration, Fiscal Year 2004-05; OPPAGA analysis.

[30] There is no upper limit on the supplemental rebate.

[31] The Pharmaceutical and Therapeutics Committee, composed of doctors and pharmacists, is required by state law to recommend the drugs that AHCA should place on the PDL.

[32] The 2001 legislation allowed drug manufacturers to offer supplemental rebates in the form of Medicaid program benefits that offset a Medicaid expenditure, such as disease management programs, drug product donation programs, and drug utilization control programs. State law was amended in 2004 to limit supplemental rebates to cash rebates.

[33] Prior to 2005, manufacturers were exempted from negotiating prices and paying supplemental state rebates for mental health drugs.

The Florida Legislature

Office of Program Policy Analysis and Government Accountability

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- Performance-based program budgeting (PB^2) reports and information offer a variety of tools. Program evaluation and justification reviews assess state programs operating under performance-based program budgeting. Also offered are performance measures information and our assessments of measures.
- Florida Government Accountability Report (FGAR) is an Internet encyclopedia of Florida state government. FGAR offers concise information about state programs, policy issues, and performance.
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Crohn's Disease & Ulcerative
Colitis Report (DOH)

The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Bureau of Epidemiology

Florida Department of Health

FLORIDA DEPARTMENT OF HEALTH

Background

- Crohn's disease and ulcerative colitis (IBD) are serious chronic disorders of the gastrointestinal tract
- Approximately 1.4 million Americans are afflicted
- No previous research conducted on IBD in Florida
- "Crohn's and Colitis Disease Research Act" (HB869 ER (Section 2)) requires the Florida Department of Health to conduct an epidemiologic study on IBD

Partners

- UF
- AHCA
- CCFA*
- Blue Cross Blue Shield
- Medical providers

* Crohn's and Colitis Foundation of America

Purpose

- Determine:
  - Prevalence of IBD in Florida
  - Demographic characteristics of IBD patients
  - Role of environmental and genetic risk factors

Implementation of the Study

- Literature review
- Consultations from experts
- Advisory Committee
- Epidemiologic study
- Information dissemination

Literature Review

- Rate of IBD
  - Crohn's disease: 162 per 100,000 to 199 per 100,000
  - Ulcerative colitis: 170 per 100,000 to 246 per 100,000

Literature Review

- Characteristics of IBD patient:
  - Females > 50%
  - Mean age at diagnosis: 33.4 - 45 years
  - Non-Hispanic Whites had a higher rate
- Factors Associated with IBD
  - Family history
  - Smoking

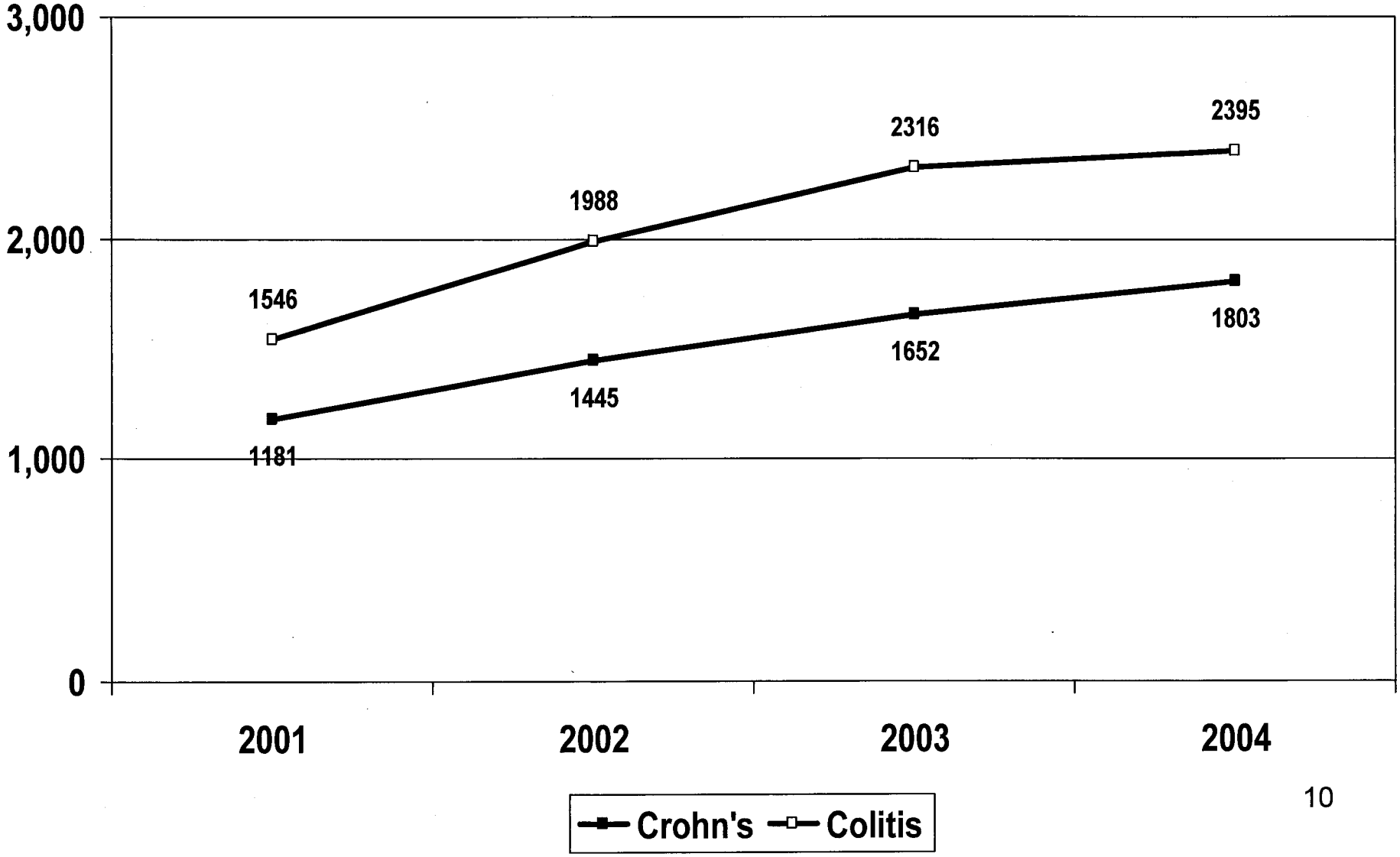
Consultations from Experts

- **CDC**: Sean Cucchi and Siobhán O'Connor
- **CCFA:** Suzanne Rosenthal, Marjorie Merrick and Florida representatives
- **University of Miami:** Amy Trachter
- **Medical College of Wisconsin:** Subra Kugathasan
- **Shafran Gastroenterology Center**: Ira Shafran
- **Kaiser Permanente:** Lisa Herrinton
- **Crohn's and Colitis support group**: David Wolff

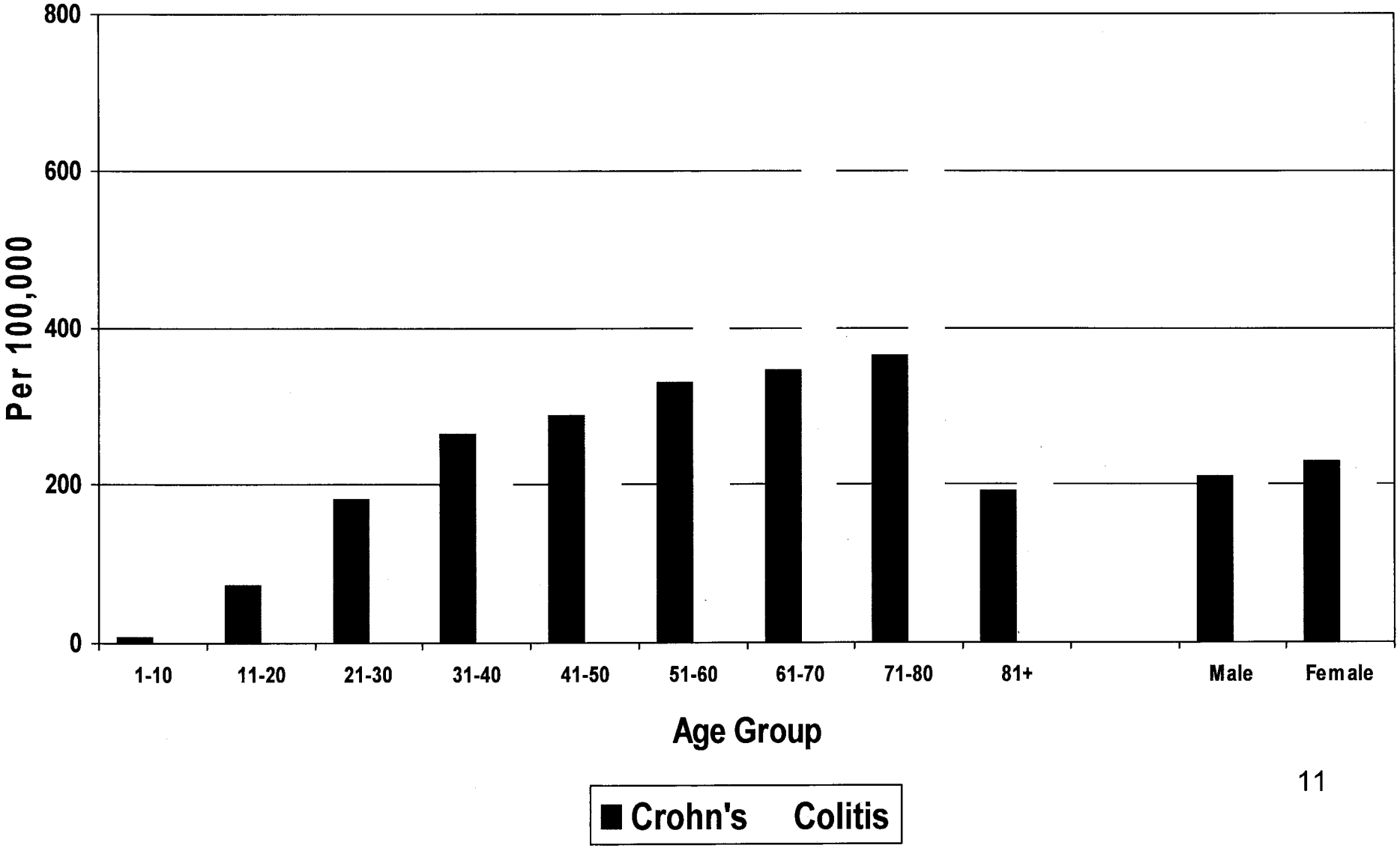
Advisory Committee

- **DOH**: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- **UF**: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine
- **AHCA**: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- **BCBS**: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- **Florida House Representative**: Eleanor Sobel
- **Florida Senate**: Gwen Margolis
- **Physician and Psychologist** : Laurence Adams, Amy Trachter
- **Tidewater Consulting, Inc.**: Frank Mayernick
- **CCFA**: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- **CDC**: Sean Cucchi and Siobhan O'Connor
- **Kaiser Permanente**: Lisa Herrinton

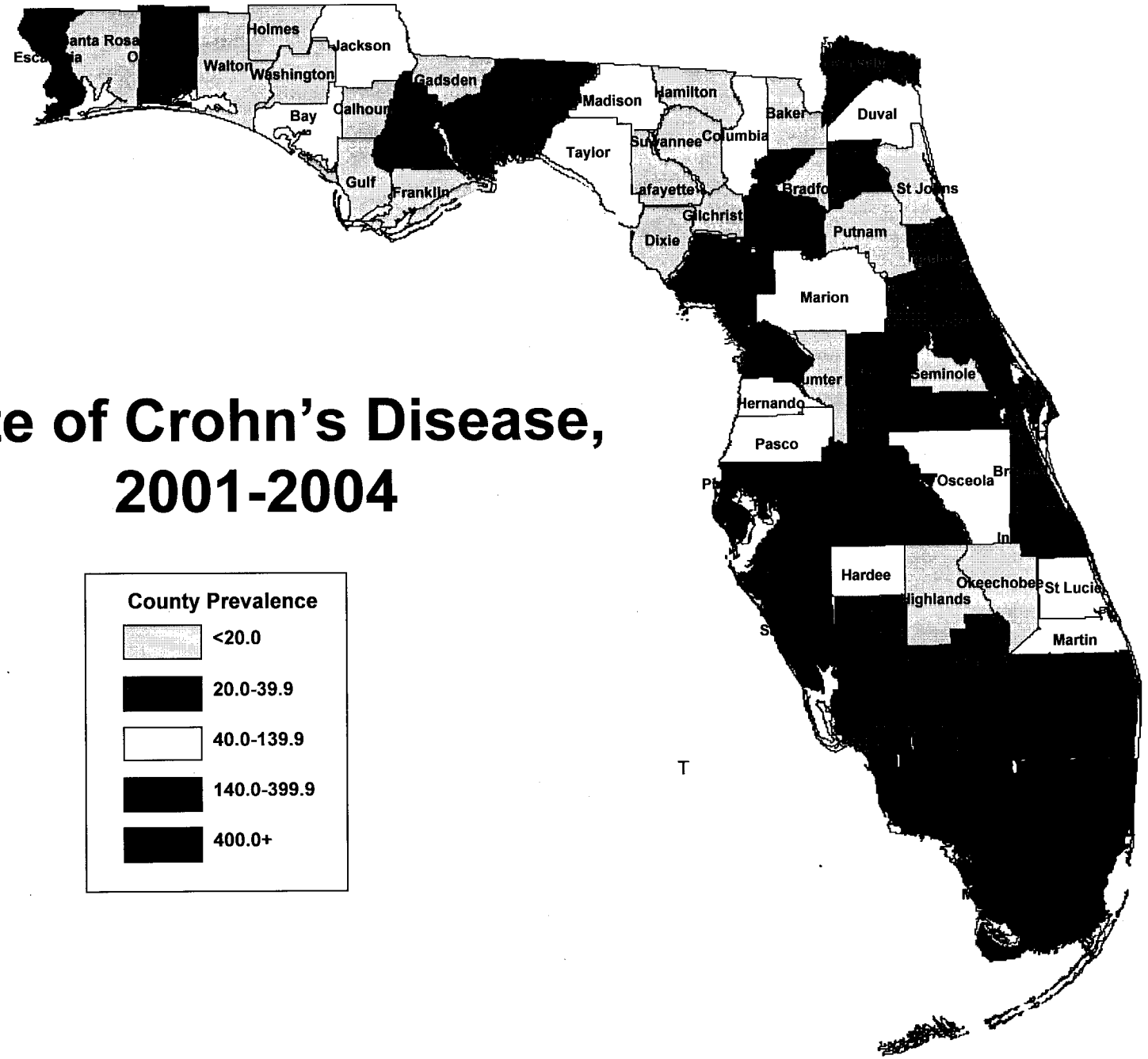
Number of New IBD Patients among BCBS Members, 2001-2004



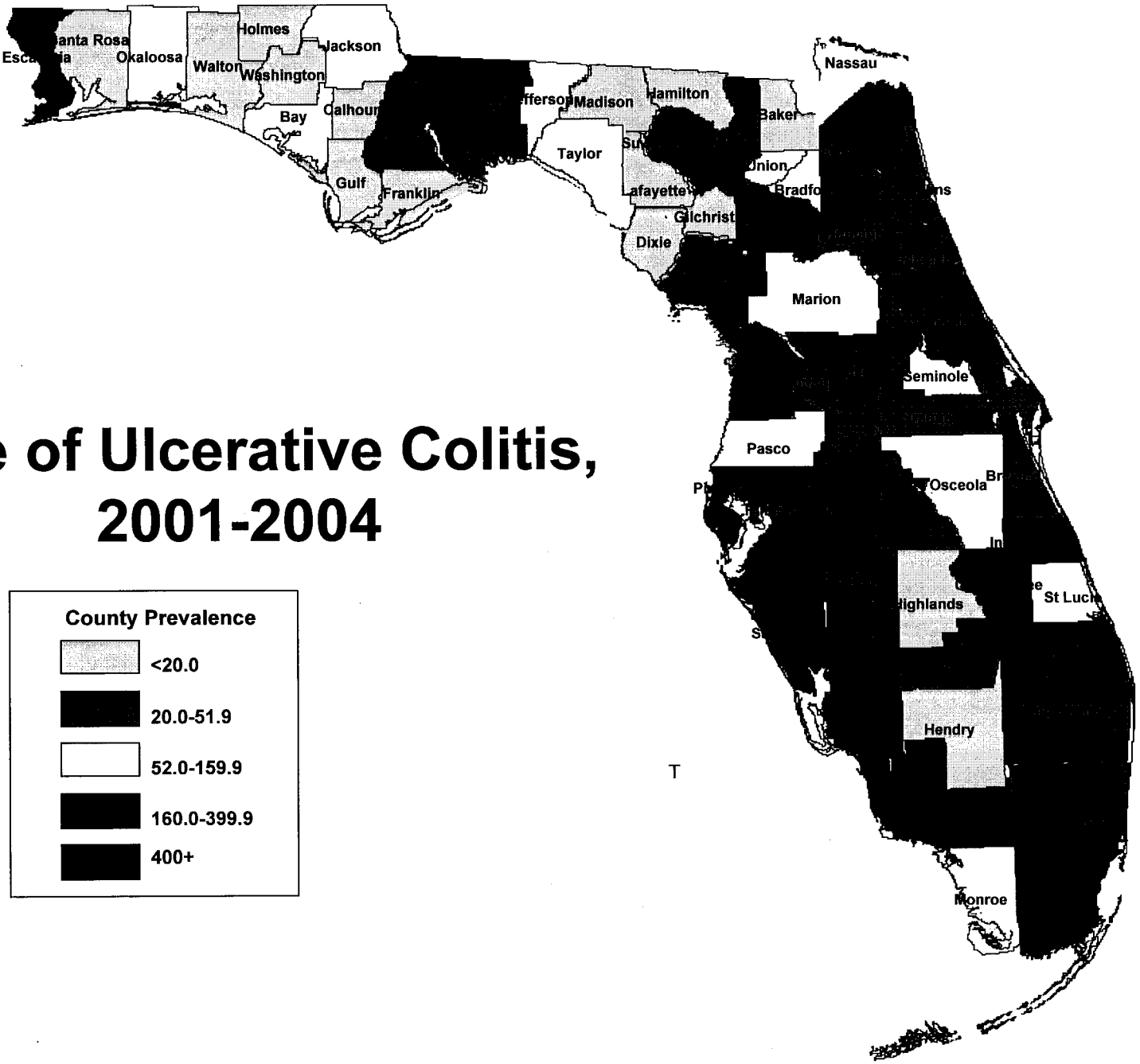
Rate of IBD among BCBS Members 2001-2004



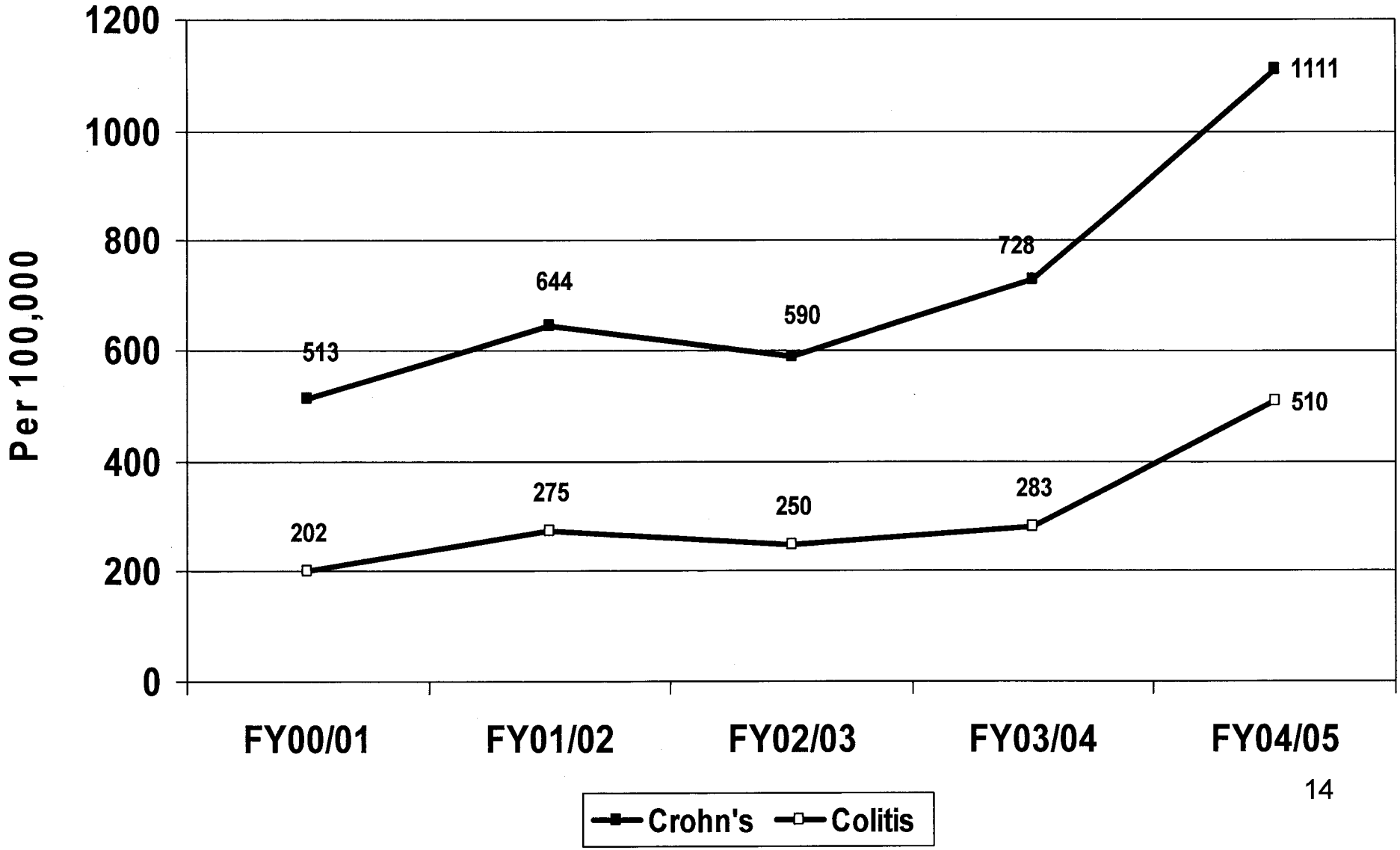
Rate of Crohn's Disease, 2001-2004



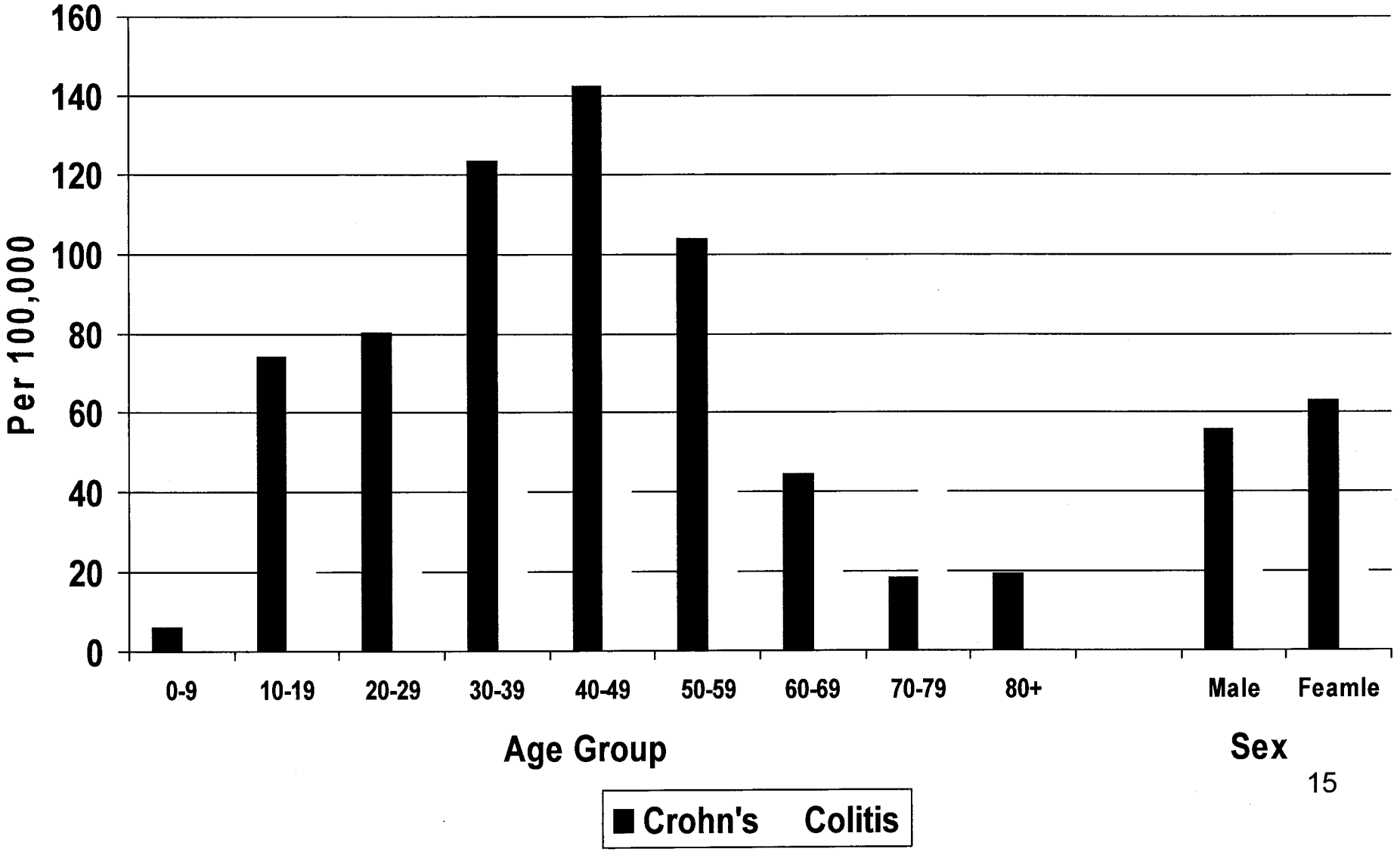
Rate of Ulcerative Colitis, 2001-2004



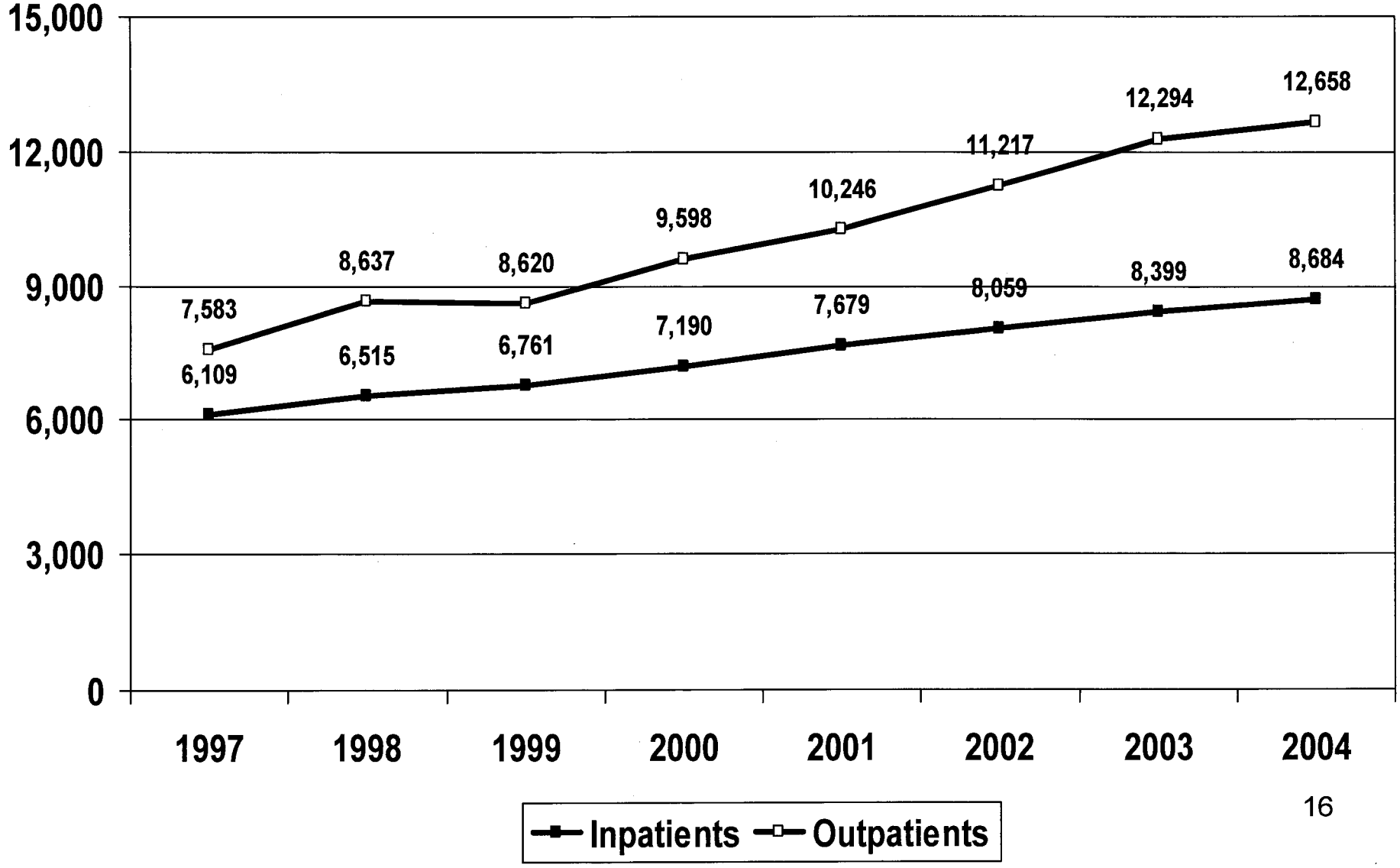
Number of New IBD Cases among Medicaid Recipients, FY00/01 – FY04/05



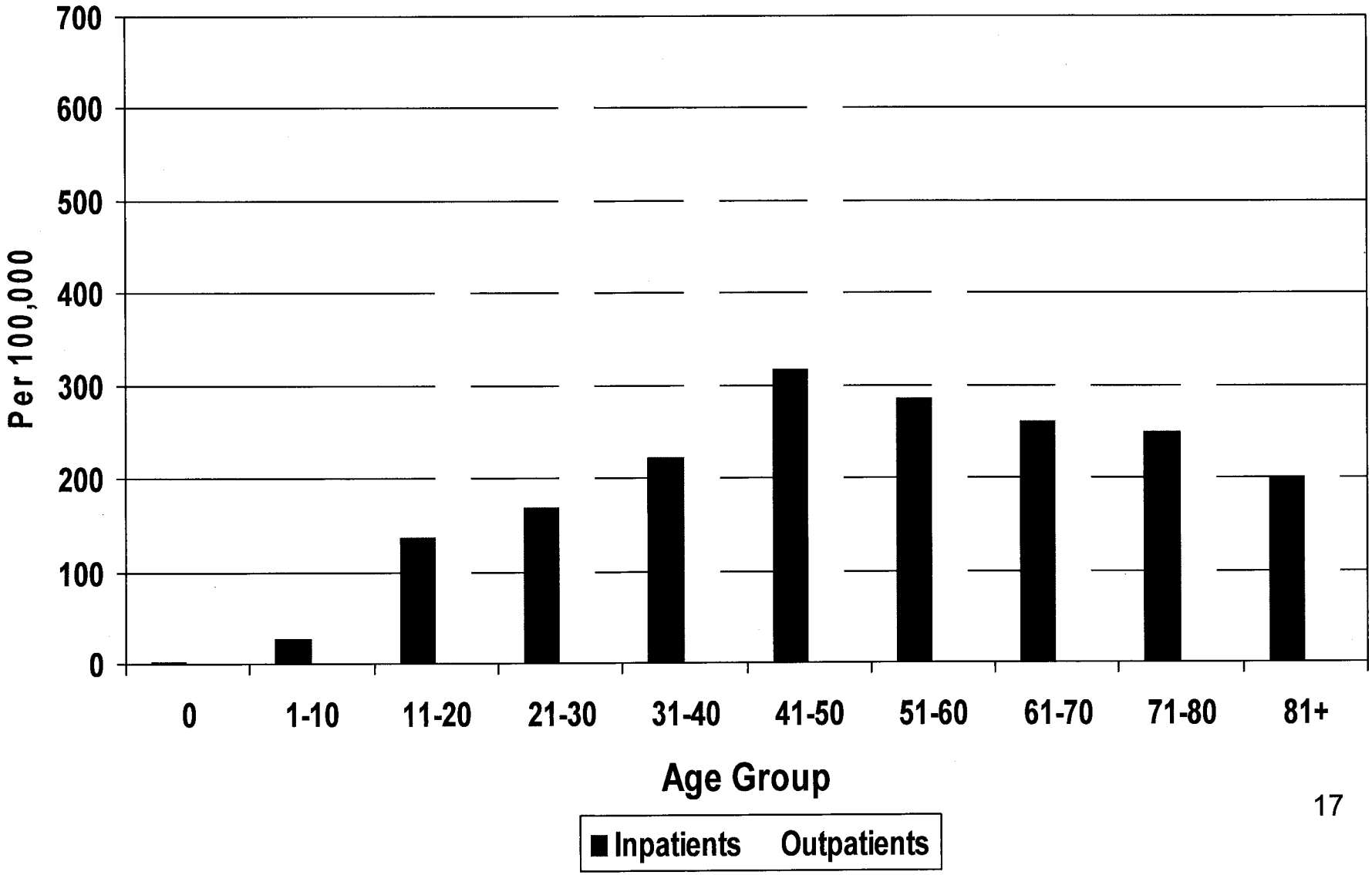
Rate of IBD among Medicaid Recipients, FY00/01- FY04/05



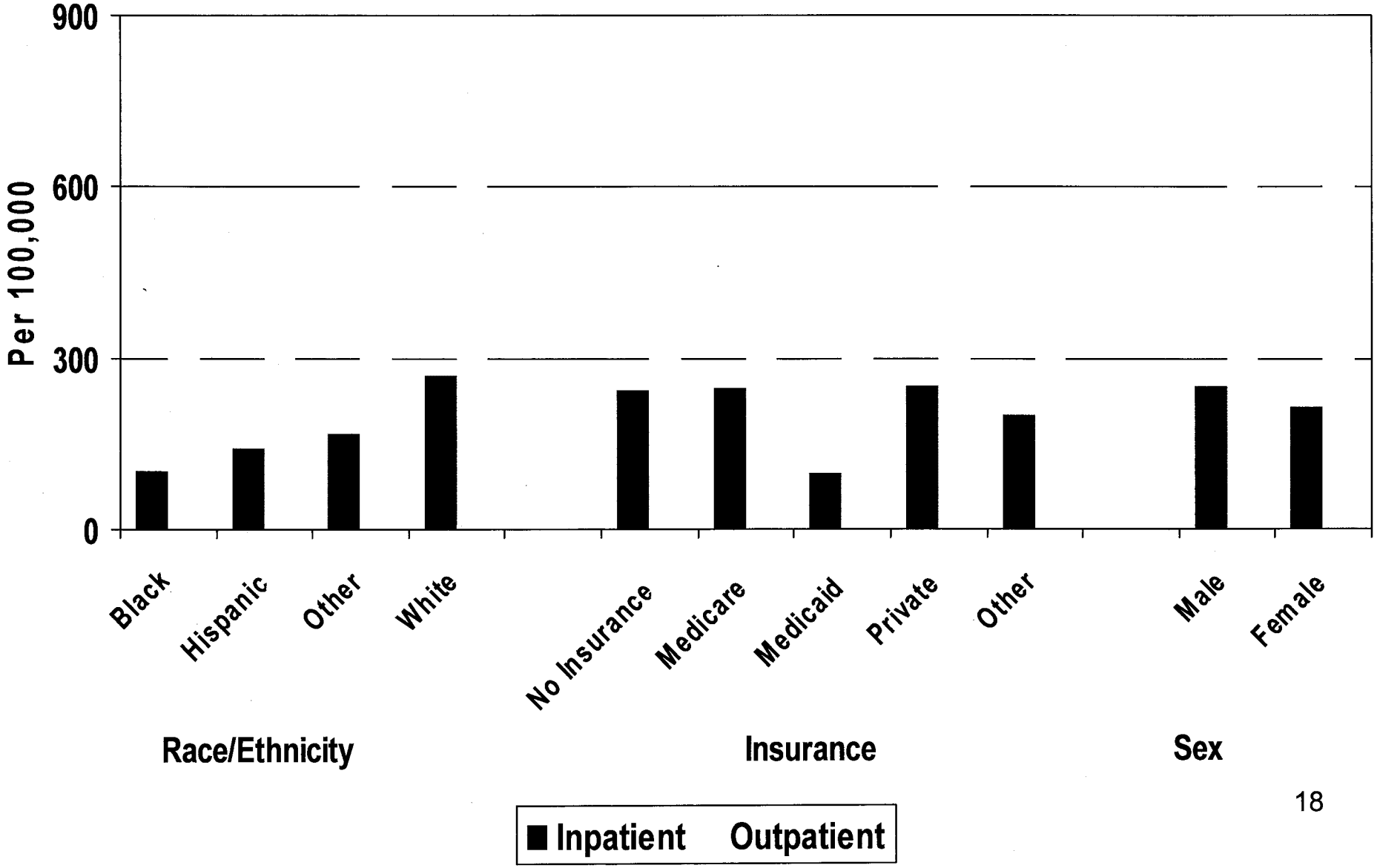
Number of IBD Inpatients and Outpatients, 1997-2004



Rate of IBD Inpatients and Outpatients, 1997-2004



Rate of IBD Inpatients and Outpatients 1997-2004



Surveys: BRFSS

- 3.8% of 1,659 survey respondents reported IBD in their household.
- 4.8% of 63 households had more than one patient
- 18.2% patients were hospitalized in the past year.

Surveys: Physicians and Patients

- 113 physicians
  - 14% diagnosed in the past 12 months;
  - 40% between age 20 and 45 years
  - 93% white and 5% African Americans
  - 22% had a family history
- 27 patients
  - Average time with IBD: 11.1 years
  - 96% whites, 33% Jewish decent
  - 18% with a family history
  - 18% rated their health as poor

Conclusions

- Estimated rate: 529 per 100,000
  - Crohn's disease: 222 per 100,000 persons
  - Ulcerative colitis: 307 per 100,000 persons
- Estimated number of patients: 84,500
  - 35,500 with Crohn's disease
  - 49,000 with ulcerative colitis

Conclusions

- The rate is higher among:
  - Young and middle age adults
  - Non-Hispanic Whites
  - Residents in Sarasota and Palm Beach counties
- Family history suggests genetic factors associated with IBD
- No environmental factors were identified or confirmed in this study

Final Report of The Epidemiologic Study on Crohn's Disease and Ulcerative Colitis

HB 869 ER (Section 2)

Prepared by

Bureau of Epidemiology
Florida Department of Health

February 1, 2006

Jeb Bush
Governor

M. Rony François, M.D., M.S.P.H., Ph.D.
Secretary, Department of Health

EXECUTIVE SUMMARY

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. On June 10, 2005, Governor Jeb Bush signed House Bill 869 entitled "Crohn's and Colitis Disease Research Act" that requires the Florida Department of Health (DOH) to conduct an epidemiologic study on IBD. The goal of this epidemiologic study is to determine: (1) the prevalence of Crohn's disease and ulcerative colitis in Florida; (2) the demographic characteristics of patients with Crohn's disease and ulcerative colitis; and (3) the role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis. The act became effective on July 1, 2005, and the final report is due on February 1, 2006.

An advisory committee was developed for the epidemiologic study. The committee members consisted of representatives and researchers at DOH, the University of Florida, Agency for Health Care Administration (AHCA), Blue Cross Blue Shield (BCBS), Crohn's and Colitis Foundation of America (CCFA), members of the House of Representatives and the Senate, physicians, other medical providers, and other interested groups. Monthly conference calls and an in-person conference were held for the committee members to guide the study.

The study was designed based on an extensive literature review of previous epidemiologic studies and recommendations from national experts. This study received support from the Secretary of the Department of Health, medical providers, and IBD patients throughout the state.

BCBS and AHCA provided large healthcare claim datasets, including BCBS data, Medicaid data, hospital discharge data, and ambulatory patient data. The DOH team conducted gastroenterology physician surveys, an IBD patient survey, and a statewide survey of general population through the Behavioral Risk Factor Surveillance System (BRFSS). The definition of IBD was based on a set of International Classification of Disease Version 9 (ICD-9) codes.

The study collected healthcare claim data with more than 42 million unduplicated records in up to 10 years, and surveyed more than 2,000 households, medical providers, and IBD patients statewide during the study period. The data were analyzed by patient's gender, race/ethnicity, age, residential county, household income, and type of health insurance. Statewide prevalence and number of IBD patients were estimated based on the data of this study and make-up of Florida population.

It is estimated that the prevalence of Crohn's disease is 222 per 100,000 persons and the prevalence of ulcerative colitis is 307 per 100,000 persons in Florida. It is also estimated that there are approximately 35,500 Crohn's disease patients and 49,000 ulcerative colitis patients in Florida. Approximately 11 percent of IBD patients are hospitalized and 12 percent of IBD patients are treated as ambulatory patients every year. The prevalence of IBD was higher among people ages 30 to 80 years old than among other age groups, higher among non-Hispanic Whites than among other race/ethnicity groups, and higher among females than among males. Medicaid recipients had the lowest prevalence rates in either inpatients or ambulatory patients. Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

This study surveyed 27 IBD patients and found a high percent of non-Hispanic Whites, a high percent of patients with a family history, and a high percent of Jewish descents, which may

suggest an association between genetic factors and IBD. The survey examined several environmental factors based on literature reviews, including exposures to cigarette smoking, history of living near cattle and history of tonsillectomy or appendectomy. However, no causal relationship could be established between these risk factors and IBD due to the nature of the small survey of a convenient sample.

Future studies are recommended based on this study. These studies include: (1) a BRFSS survey with increased sample size to better estimate the population-based prevalence of IBD; (2) a case-control study to identify risk factors of IBD; and (3) an IBD patient voluntary registry through their providers. This registry will provide data for a longitudinal follow-up study of IBD patients on treatment, outcome, and quality of life.

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BACKGROUND

Crohn's disease and ulcerative colitis, collectively known as Inflammatory Bowel Disease (IBD), are serious chronic disorders of the gastrointestinal tract. Approximately 1.4 million Americans are afflicted with these illnesses, 30 percent of whom are diagnosed during childhood. IBD represents a major cause of morbidity from digestive illness, and ulcerative colitis patients are at high risk for developing colorectal cancer. Although IBD is rarely fatal, it is often devastating.

On November 30, 2004, President George W. Bush signed into law the first piece of legislation focused on Crohn's disease and ulcerative colitis, entitled the "Research Review Act." During the 108th Congress, the Crohn's and Colitis Foundation of America and its National IBD Advocacy Network advanced this legislation with three provisions for advancing research on IBD. Provisions were taken directly from legislation, entitled the "Inflammatory Bowel Disease Research Act." Within 12 months after the date of the enactment, the director of the Centers for Disease Control and Prevention was responsible for submitting a comprehensive plan to address the burden of inflammatory bowel disease, in both adult and pediatric populations, to the Senate Health, Education, Labor and Pensions Committee, the House Energy and Commerce Committee, and the House and Senate Appropriations Committee.

There is a perceived increase of IBD in Florida; however, no previous research has been conducted to reveal the prevalence of these illnesses among Florida residents. Therefore, the Florida State Legislature enacted the "Crohn's and Colitis Disease Research Act."

On June 10, 2005, Florida House Bill 869 was approved by Governor Jeb Bush. House Bill 869 is referred to as the "Crohn's and Colitis Disease Research Act." The act requires the Florida Department of Health (DOH) to conduct an epidemiologic study on inflammatory bowel disease in collaboration with the University of Florida College of Public Health and Health Professions, and requires the establishment of an IBD study group that must consist of representatives from the DOH, the Agency for Health Care Administration (AHCA), Crohn's and Colitis Foundation of America (CCFA), the House of Representatives, the Senate, medical providers, and other interested groups. The effective start date is July 1, 2005, and the final report is due to the Governor and the Florida Legislature by February 1, 2006.

PURPOSE OF THE STUDY

The purpose of this study is to work with the University of Florida and other agencies and organizations to conduct an epidemiologic investigation. The goal of this epidemiologic study is to determine the:

1. Prevalence of Crohn's disease and ulcerative colitis in Florida.
2. Demographic characteristics of patients with Crohn's disease and ulcerative colitis.
3. Role of environmental and genetic risk factors in the development of Crohn's disease and ulcerative colitis.

IMPLEMENTATION OF THE STUDY

Literature Review

As the first step of study design, DOH conducted an extensive literature review for studies on IBD. The project coordinator searched the Internet and journals to identify previous epidemiologic studies on both adult and childhood IBD. Through the literature review, DOH gathered information regarding potential and known IBD risk factors, epidemiologic and clinical characteristics of patients with IBD, and potential environmental exposures for IBD.

Drs. Robert Sandler and Edward Loftus (Sartor RB, Sandborn WJ, eds., Kirsner's *Inflammatory Bowel Diseases*, 6th ed., New York: Saunders, 2004) reviewed risk factors for IBD, including demographic characteristics of patients, diet, breast feeding and perinatal events, marital status, occupation and social class, oral contraceptives, cigarette smoking, non steroidal anti-inflammatory drugs, appendectomy, measles, and other miscellaneous factors. Sandler and Loftus conclude that there is undisputable evidence of heritable factors in the genesis of IBD, and environmental influence may attribute to 85-90 percent in ulcerative colitis and 50-55 percent in Crohn's disease. Smoking is highly associated with Crohn's disease, as is nonsmoking with ulcerative colitis. Truelove (Br Med J 1961:1:61) noted cow's milk might exacerbate symptoms of ulcerative colitis.

Dr. Edward Loftus (Gastroenterology, 2004:126:1504-17) states that previous studies have provided insight into the differences in incidence of IBD across age, time, and geographic region, suggesting that environmental factors can significantly modify the expression of these conditions. They suggest the strongest risk factors to be identified at this time are family history of IBD, cigarette smoking, and appendectomy. Research also suggests variation in the demographics of IBD patients:

- Gender: Females tend to have a predominance of Crohn's disease, whereas men tend to have a higher incidence of ulcerative colitis.
- Age: Both Crohn's disease and ulcerative colitis are most commonly diagnosed in late adolescence and early adulthood, however, the diagnosis may occur at any age.
- Race/Ethnicity: Although Whites have a higher incidence of IBD, the incidence among African Americans is approaching that of Whites. Asian Americans, Hispanic Americans, and aboriginal North Americans are less likely to develop IBD, especially Crohn's disease. Ethnic and racial differences may be more related to lifestyle and environmental influences than genetic differences.

Consultations from Experts

In addition to the literature search, DOH sought national and local experts to provide insights for developing Florida's IBD research plan. The project coordinator and the team consulted with many researchers nationwide for research methodology. The information received from these experts helped the Florida researchers refine the methodology of the IBD study. From August through December of 2005, DOH communicated with the following individuals and organizations for their suggestions and advice:

- Mr. Sean Cucchi and Dr. Siobhán O'Connor, Centers for Disease Control and Prevention (CDC), discussed the "Inflammatory Bowel Disease Research Act," which requires the CDC, in conjunction with CCFA, to conduct a national IBD epidemiology study. DOH requested information regarding CDC's research approach and methodology for data collection at the national level.

- Ms. Suzanne Rosenthal, CCFA Co-Founder, and Chairman of the Board Emeritus, and Marjorie Merrick, CCFA Vice President of Research and Scientific Programs provided contact information for national IBD experts, potential funding sources, and guidance in developing methodology.

- Florida CCFA representatives provided contact information for Florida physicians, IBD support group facilitators, and IBD awareness activities.

- Dr. Robert Sandler, Chief, Division of Gastroenterology and Hepatology at the University of North Carolina, and member of CCFA's National Scientific Committee, provided information on IBD epidemiological literature, former IBD study group activities, survey development, and future research development.

- Dr. Amy Trachter, Assistant Professor of Clinical Medicine, Department of Medicine Division of Gastroenterology, Miller School of Medicine University of Miami, provided revisions to patient survey and disseminated surveys to IBD patients. Dr. Trachter also offered additional support for developing grant proposals and future IBD research.

- Dr. Subra Kugathasan, Associate professor, Pediatrics, Medical College of Wisconsin, discussed resources imperative for the development and maintenance of a pediatric IBD registry.

- Dr. Ira Shafran, Shafran Gastroenterology Center, provided the "Inflammatory Bowel Disease Questionnaire Treatment Evaluation Form," a survey administered to patients at the Gastroenterology Center.

- Dr. Lisa Herrinton (Co-PI of IBD study funded by CCFA) of Kaiser Permanente Division of Research, provided information regarding research approach and methodology of two CCFA-funded epidemiological studies. She also shared with DOH the prevalence of IBD among nine health plans across the United States (U.S.), and incidence and prevalence of IBD at Kaiser Permanente, Northern California.

- Mr. David Wolff, Crohn's and Colitis support group facilitator, provided information about IBD patients and the daily implications of living with these illnesses. Mr. Wolff gave insight for the development of a pilot patient survey and assisted in the distribution of surveys to support group members.

Advisory Committee

The study advisory group (a.k.a. Advisory Committee) consisted of epidemiologists at DOH, analysts at AHCA and Blue Cross Blue Shield, physicians and researchers at the University of Florida, members of the House of Representatives and the Senate, representatives from CCFA, medical providers, and other interested groups. The group welcomed any interested organization or individual to participate in the study group.

The first Advisory Committee conference call was held on June 14, 2005. Representatives from the DOH and the University of Florida (UF) participated in the conference call. The group decided to appoint a coordinator, develop an advisory committee, conduct monthly conference calls, and schedule an in-person meeting for advisory members. The group also approved the data collection methodology proposed by the DOH.

Regan Glover of the DOH was appointed as the project coordinator on July 18, 2005.

A letter of invitation to join the Advisory Committee was sent to medical providers, the legislature, representatives from Blue Cross Blue Shield of Florida, state and national Crohn's and Colitis Foundation of America representatives, and the Agency for Health Care Administration. Those interested in joining the committee and/or following the study were placed in a contact database.

Members of the Advisory Committee, consultants, and analysts for this study are:

- AHCA: Gloria Barker, Mel Chang, Susan Chen, Beth Eastman, Adrienne Henderson, Lisa Rawlins, and Cliff Schmidt
- BCBS: John Bookstaver, Randy Kammer, John Montgomery, David Pizzi, and John Williams
- CDC: Sean Cucchi and Siobhan O'Connor
- CCFA: Kiren Annigeri, Marlene Bluestein, Toby Gordon, Marjorie Merrick, Suzanne Rosenthal, Allison Silver, Ellen Shapiro, Kelly Stouten, and Dave Wolff
- DOH: Lisa Fisher, Regan Glover, Youjie Huang, Curt Miller, Heather Murphy, Mike Paredes, and Dian Sharma
- Florida House Representative: Eleanor Sobel
- Florida Senate: Gwen Margolis
- Kaiser Permanente: Lisa Herrinton
- Tidewater Consulting, Inc.: Frank Mayernick
- Physician: Laurence Adams
- Psychologist: Amy Trachter
- UF: Paul Duncan, Chris Jolley, Robert Frank, and John Valentine

Conference calls were held on August 11, September 1, October 6, November 3, 2005, and January 18, 2006. Representatives from a number of agencies, universities, and organizations, as well as interested individuals, participated in the conference calls. The Advisory Committee provided recommendations for the following issues:

- Requirements of House Bill 869.
- Identification of additional members for the study advisory group.
- Plan of study, including overall approach and timeline.
- Diagnoses and procedure codes (ICD-9) for identifying IBD cases in claim data.
- Methods of conducting a survey of GI physicians and IBD patients.
- Development of the pediatric survey and cover letter.
- Survey questions to be added to statewide Behavioral Risk Factor Surveillance System (BRFSS).
- Progress of the study, including data analyses and survey response.
- Preliminary findings of the study.

On November 15, 2005, the Advisory Committee had an in-person meeting in Gainesville, Florida. The participants reviewed preliminary findings and discussed strengths/limitations of study methods and potential sources of data dissemination.

Information Dissemination

The DOH Bureau of Epidemiology made great efforts to disseminate the information regarding the study, including the purpose, methods, and preliminary results to public health professionals, medical providers, Advisory Committee members, and the general public during the entire study period.

- To public health professionals:
  - The Bureau published an article introducing the new research in *Epi Update* in July 2005. *Epi Update* is a web-based weekly journal published by the Bureau of Epidemiology. A follow-up article to update the progress of the study was published in *Epi Update* in September 2005.
  - The study was introduced to county health departments on a bi-weekly conference call in August 2005.
  - An overview of the IBD study was submitted to The Health Advisor, which is the forum to spotlight Department of Health special events, people, programs, and statistics. The newsletter is sent to county health departments, Department of Health units, legislators, and others involved in health around the state and country. The article will appear in the January/February 2006 issue.

- To Advisory Committee members:
  - Plans, progress of the implementation of the study, and preliminary results were provided to, and reviewed by, the Advisory Committee at monthly conference calls and the in-person meeting in November.

- To Medical providers:
  - The study was introduced to gastroenterologists at the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples, Florida, on September 9-11, 2005.

- To interested groups and individuals:
  - The project coordinator presented preliminary findings for Crohn's Disease at the CCFA Fourth Annual Advances in IBD Research in Miami Beach, Florida, in December 2005.
  - Per suggestion from a spokesperson for the national chapter of CCFA, a letter was sent to former first lady, Barbara Bush, introducing the Florida IBD study and inviting her to attend a meeting where the findings from this study will be presented.
  - Frequent conversations were maintained via e-mails and phone calls between the project coordinator and IBD support groups in the state.

METHODS

Sources of Data

When sources of population-based data were identified, the DOH research team found that all databases available were developed for purposes other than IBD epidemiologic study, and not a single database was available that would meet the specific needs for this study. Therefore, the

research team decided to collect a number of large databases that each covers part of the IBD population and then combine the information from these databases for a comprehensive result.

The data included in this study consisted of healthcare claim data (hospital discharge data, ambulatory care data, Blue Cross Blue Shield data, and Medicaid data), and survey data (physician survey, patient survey, and BRFSS survey). Collectively, these data covered a majority of the Florida population and provided a well-represented prevalence of IBD in Florida.

Blue Cross Blue Shield (BCBS) claim data

BCBS of Florida provided claim data for their members from calendar years 2001 to 2005. BCBS is one of the major private health insurance carriers, with approximately 30 percent of Florida's commercial market share. More than 2.5 million BCBS members in Florida receive medical services every year. BCBS members consist of males and females of all ages and races. A majority (more than 80 percent) of members who had a claim record are under the age of 65. Claim data capture information on hospitalizations and clinic visits.

The data were unduplicated to provide the number of patients, instead of the number of medical services. Therefore, if a patient with IBD had more than one visit, he or she was only counted once during the data collection timeframe. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555.9), chronic proctitis (556.2), chronic sigmoiditis (556.3), colitis (556.8, 556.9), enteritis (555.0, 555.1), ileitis (555.2), and other and unspecific colitis (558.9). Data were broken down by patient's age, sex, and residential county.

The DOH included data in four years (2001-2004) in this study, with 10,970,547 person-years. On average, 2,742,637 BCBS members were included in the data each year during 2001-2004.

Medicaid data

Medicaid claim data in fiscal years (FYs) 2000-2004 were provided by AHCA. Medicaid data included all claims, both hospitalizations and clinic visits, for more than one million Medicaid recipients in Florida. Medicaid recipients consist of people of all ages, with more than 50 percent of recipients who are under age 20.

The data were unduplicated to count only the number of patients who received medical care. Disease diagnoses were grouped into several categories: Crohn's disease (ICD-9 code: 555), ulcerative colitis (ICD-9 code: 556), and other IBD (ICD-9 code: 558). Data were broken down by patient's age, sex, and residential county.

Data in all five years (FYs 2000-2004) were included in the study. The data contain 5,922,697 person-years of records, with an average of 1,184,539 recipients each year.

Ambulatory patient data

AHCA provided ambulatory patient data for fiscal years1997-2004. The ambulatory patient data are collected from freestanding ambulatory surgical centers, lithotripsy centers, cardiac catheterization laboratories, and short-term acute care hospitals. Ambulatory patients are those who have a face-to-face encounter with a provider, and who are not formally admitted

as an inpatient in an acute care hospital setting, and not treated in the emergency room. The ambulatory patient data include patients of all ages and races, regardless of the type of a patient's medical insurance.

Disease diagnoses were grouped into several categories based on either primary diagnosis or any of the secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all eight years were included in the analysis. There were 12,710,291 patient records analyzed, with an average of approximately 1.6 million patients every year. Patients might have more than one ambulatory visit either in a single year or in different years. The DOH unduplicated multiple visits in two ways: 1) to count each patient only once for the entire 8-year period for number of "new" IBD patients among ambulatory patients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among ambulatory patients. Data were analyzed by race, age, residential county, and type of medical insurance.

Hospital discharge data

AHCA also provided hospital discharge data for 1995-2004. The hospital discharge data include all inpatients of all ages and types of medical insurance.

Disease diagnoses were grouped into several categories based on either primary or secondary diagnoses. These categories are Crohn's disease, ulcerative colitis, and other colitis.

Data in all 10 years were included in the analysis. There were 12,769,086 inpatient records analyzed, with an average of approximately 1.2 million patients every year. Many patients had more than one hospitalization either in a single year or in different years. The DOH unduplicated multiple hospitalizations in two ways: 1) to count each patient once in the entire 10-year period for number of "new" IBD patients among inpatients; and 2) to count each patient once in a single year for an annual prevalence of IBD patients among inpatients.

IBD inpatients who had ambulatory visit(s) were excluded from the analyses to avoid duplication for patients receiving medical care in hospitals. Data were analyzed by race, age, residential county, and type of medical insurance.

Gastroenterology (GI) Physician survey

DOH Bureau of Epidemiology developed a gastroenterology (GI) physician survey in August 2005. (See attachment 1 for the survey questionnaire.) The survey was designed to estimate:

- Patient demographics
- Number of newly diagnosed IBD cases within past 12 months
- Severity of illness measured by hospitalizations due to IBD
- Role of family history
- Patient's enrollment for colon cancer surveillance

The survey questionnaire was sent to 660 gastroenterologists in Florida by mail. The DOH research team received 132 returned survey questionnaires, among which 113 were completed.

Regan Glover, the project coordinator, distributed the survey questionnaires at the general sessions of the 40th Annual Meeting of the Florida Gastroenterological Society and the American College of Gastroenterology in Naples Florida on September 9-11, 2005. Ten completed surveys were received from the conference attendees.

Pediatric GI physician survey

The Bureau of Epidemiology revised the GI-physician survey questionnaire to address pediatric IBD patients seen by pediatric specialists. Data collected were similar to that collected from the GI physician survey. Survey questionnaires were distributed to 41 Florida members of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) via mail. A cover letter and pre-paid return envelope were included with the mailed survey. Collection period began September 26, 2005, and ended on October 26, 2005. Eight (20 percent) of 41 physicians returned completed survey questionnaires.

IBD patient survey

The DOH team developed a short anonymous survey of IBD patients. (See attachment 2 for the questionnaire.) Dr. Amy Trachter and GI physicians assisted with the design of questionnaire. The purpose of this survey was to obtain information on risk factors of IBD, particularly environmental factors and genetic factors.

The survey was implemented from December 23, 2005, to January 10, 2006. To keep responses anonymous, the DOH did not disseminate directly surveys to IBD patients. Instead, the survey questionnaire was emailed to facilitators of eight CCFA support groups. The facilitators were asked to distribute the survey questionnaire to their group members though e-mails. The total number of IBD patients who received the questionnaire from their support group facilitator was unknown. IBD patients who were willing to participate in the survey completed survey and returned surveys to DOH either electronically (e-mail/fax), or by U.S. Postal Service. The DOH received 27 completed survey questionnaires from IBD patients with two support groups in Miami and Sarasota.

Behavioral Risk Factor Surveillance System survey

The Behavioral Risk Factor Surveillance System (BRFSS) survey is a statewide random telephone survey of civilian, non-institutionalized adults (age 18 and older). The BRFSS is an ongoing collaborative survey with the CDC to monitor trends in risk behaviors related to preventable chronic diseases and conditions in Florida. Respondents are asked about health status, health behaviors, use of screening services, and access to health insurance and health care.

Three questions were designed by the Bureau of Epidemiology to survey the general population. These questions are:

- (Q1) Has anyone, including yourself, in your household, ever been told by a doctor or other health professional that you have Crohn's disease or ulcerative colitis?

- (Q2) How many people in your household have been told that they have Crohn's disease or ulcerative colitis?
- (Q3) How many of these people have been admitted to a hospital in the past 12 months because of Crohn's disease or ulcerative colitis?

The purpose of these questions is to assess the prevalence of IBD (Q1), familial aggregation of IBD cases (Q2), and severity of IBD (Q3) among general population. These questions were included in the BRFSS survey from September 1, 2005, through December 15, 2005. There were 1,847 individuals surveyed, among whom 1,678 responded to these three questions.

Medicare data were requested in October 2005; however, approval to use those records was not received as of the date of this report.

Definition of IBD

The following are the International Classification of Disease Version 9 (ICD-9) codes that were used to define Crohn's disease, ulcerative colitis, and other IBD in healthcare claim data:

Crohn's disease:

555.0: Ileitis (regional, segmental) and Regional enteritis or Crohn's disease of duodenum, ileum, or jejunum
555.1: Colitis (granulmatous, regional, or transmural) and regional enteritis or Crohn's disease of colon, large bowel, or rectum
555.2: Ileitis
555.9: Crohn's disease NOS

Ulcerative Colitis:

556.0: Ulcerative (chronic) enterocolitis
556.1: Ulcerative (chronic) ilecocolitis
556.2: Ulcerative (chronic) proctitis
556.3: Ulcerative (chronic) proctosigmoiditis
556.5: Left-sided ulcerative (chronic) colitis
556.6: Universal ulcerative (chronic) colitis
556.8: Other ulcerative colitis
556.9: Ulcerative colitis, unspecified.

Other IBD:

558.9: Other and unspecified (noninfectious gastroenteritis and colitis)

Procedure code:

45.23: Colonoscopy

Analysis

The primary purpose of analysis was to identify prevalence of IBD, patients' characteristics, and IBD related risk factors. The DOH team did not attempt to make comparisons of prevalence among subpopulations. Therefore, the team did not conduct any statistical tests for difference

in prevalence among subpopulations, nor to adjust prevalence by age-distribution of the population. The methods that the DOH used for this study were:

1. Claim data
   a. Numbers of patients with IBD were tabulated.
   b. Prevalence of IBD was estimated in various populations. Prevalence is the proportion of the population with IBD in a specific year. The prevalence was calculated as follows:
      i. BCBS data and Medicaid data: by sex and age
      ii. Hospital discharge data and ambulatory patient data: by sex, age, race, and ethnicity, and type of insurance
   c. Incidence of IBD was estimated for BCBS IBD patients. Incidence is the number of new cases diagnosed per 100,000 persons in a year. Although BCBS data counted only new patients to the BCBS system in the four-year period, some of "new" patients might have been diagnosed before the study period.
   d. Proportion of IBD patients with a colonoscopy was calculated.

2. BRFSS survey data
   Prevalence of IBD was estimated by race and household income. The prevalence was not weighted by the probability of respondents being selected for the survey because the weight variable was not available during preparation of this report. Responses of "don't know" or "unsure" were excluded from analyses.
3. Physician survey
   Percents of responses were tabulated for estimates of:
   a. Newly diagnosed cases (within past 12 months)
   b. Patient demographics
   c. Severity of illness (hospitalizations)
   d. Role of family history
   e. Colon cancer surveillance

4. Patient survey
   Percents of responses were tabulated for estimates of:
   a. Patient demographics (sex, race/ethnicity and region)
   b. Age of diagnosis/time lived with IBD
   c. Type of IBD (Crohn's disease and ulcerative colitis)
   d. Severity of symptoms (mild, moderate, severe)
   e. Presence of family history
   f. Risk behaviors (active or passive inhalation of cigarette smoke)
   g. General assessment of health

There was a close collaboration among BCBS, AHCA, and DOH representatives and data analysts for this study. John Montgomery, John Williams, and John Bookstaver provided information on BCBS and conducted analyses of BCBS claim data. AHCA representatives Mel Chang, Beth Eastman, Susan Chen, Gloria Barker, Adrienne Henderson, and Cliff Schmidt provided support and conducted analyses on Medicaid data, hospital discharge data, and ambulatory patient data. DOH epidemiologist Youjie Huang and health data analyst Curt Miller analyzed the survey data and conducted part of the analyses of hospital discharge data and ambulatory patient data.

RESULTS

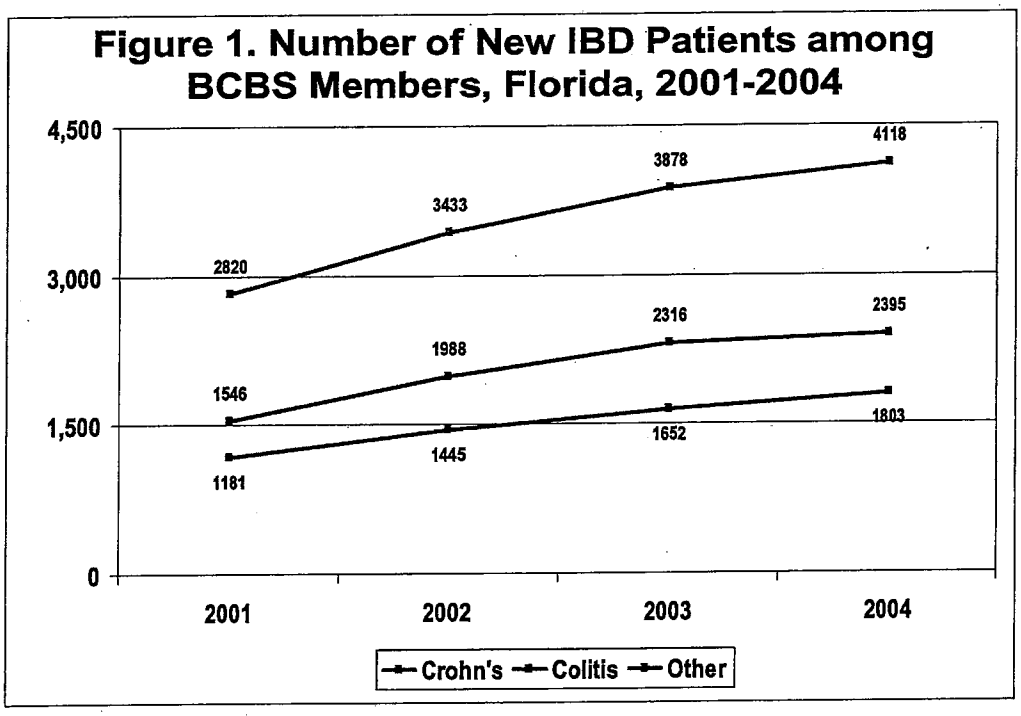
BCBS data

During 2001-2004, 6,373 BCBS members were diagnosed with Crohn's disease and 8,658 were diagnosed with ulcerative colitis. In the BCBS claim data, an average of 2,742,637 BCBS members per year received medical services. Among those members, 1,520 members, on average, were diagnosed with Crohn's disease and 2,061 were diagnosed with ulcerative colitis per year. (Table 1)

Table 1. Average Number of BCBS Members with IBD per Year, Florida, 2001-2004

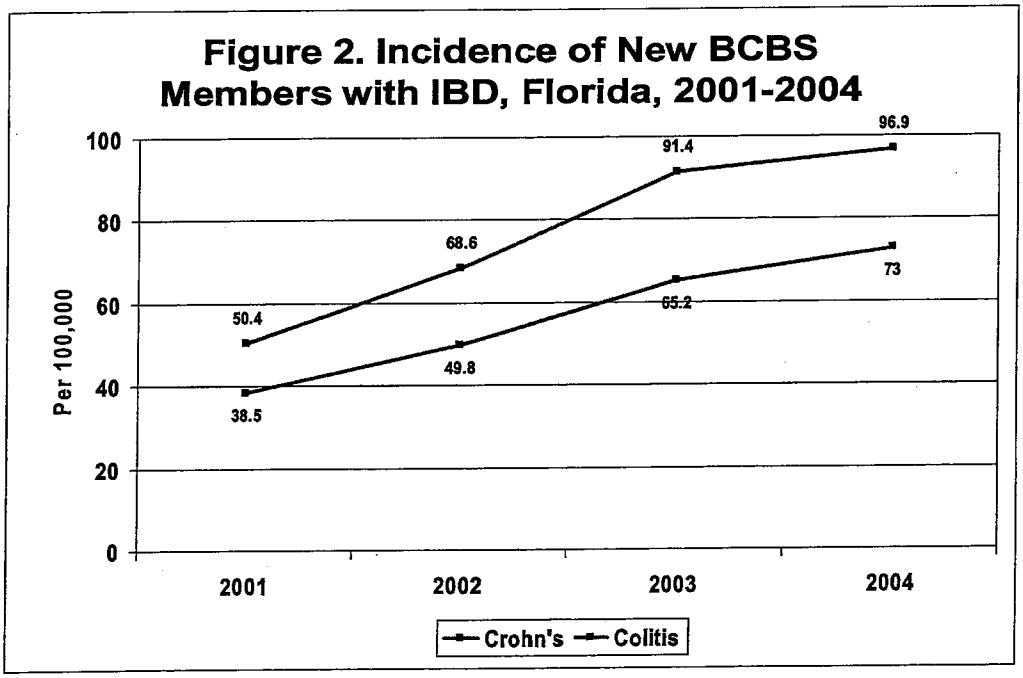
	All IBD	Crohn's	Colitis	Other	# of Members
Total	7,144	1,520	2,061	3,563	2,742,637
By Age Group					
1-10	25	7	9	10	289,104
11-20	196	81	48	68	431,765
21-30	472	150	131	180	350,594
31-40	841	234	258	349	352,003
41-50	1,231	287	381	563	398,637
51-60	1,464	305	420	738	370,815
61-70	1,294	222	388	684	256,748
71-80	1,144	156	311	677	170,573
81+	430	59	102	269	122,395
By Sex					
Male	3,006	684	956	1,365	1,296,831
Female	4,091	826	1,092	2,173	1,445,806

Number of members who were first time diagnosed with Crohn's disease increased by 55 percent from 1,546 in 2001, to 2,395 in 2004. Similarly, the number of members diagnosed with ulcerative colitis increased by 53 percent from 1,181 in 2001, to 1,803 in 2004, and the number of patients diagnosed with other colitis increased by 45 percent from 2,820 in 2001, to 4,118 in 2004 (Figure 1).



The overall four-year prevalence was 222 per 100,000 persons for Crohn's disease, 301 per 100,000 persons for ulcerative colitis, and 520 per 100,000 persons for other IBD.

The incidence (number of new patients among 100,000 people at risk in a year) increased during the four-year period. For Crohn's disease, the rate increased by 92 percent from 50.4 per 100,000 to 96.9 per 100,000 person. The prevalence of ulcerative colitis increased by 90 percent. (Figure 2)

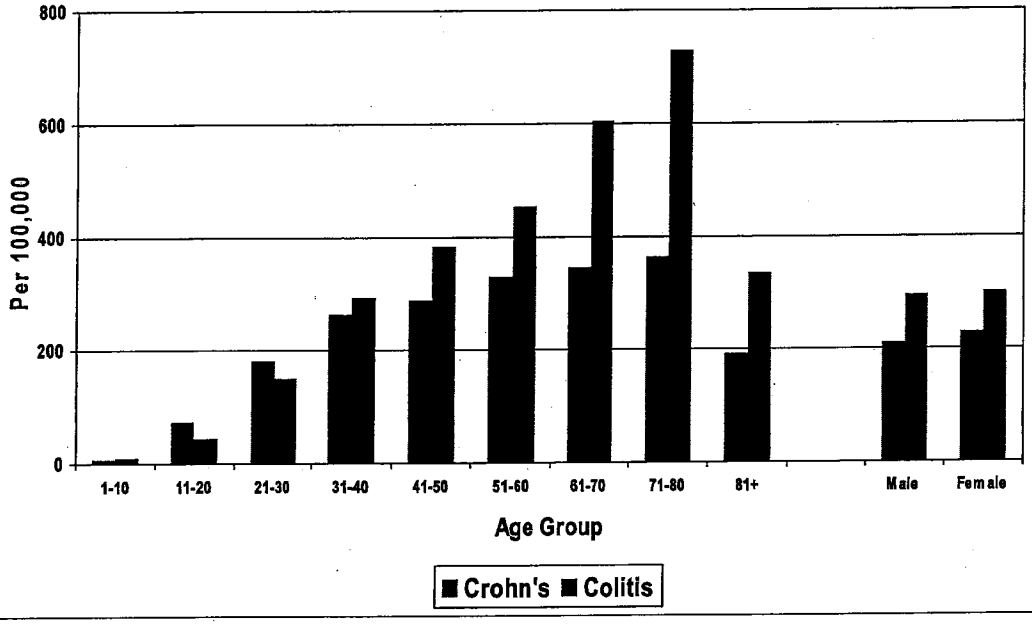


During the four-year period, the number of patients diagnosed with Crohn's disease and ulcerative colitis increased by age, and reached a peak in the 51-to-60–year-old age group (Table 1).

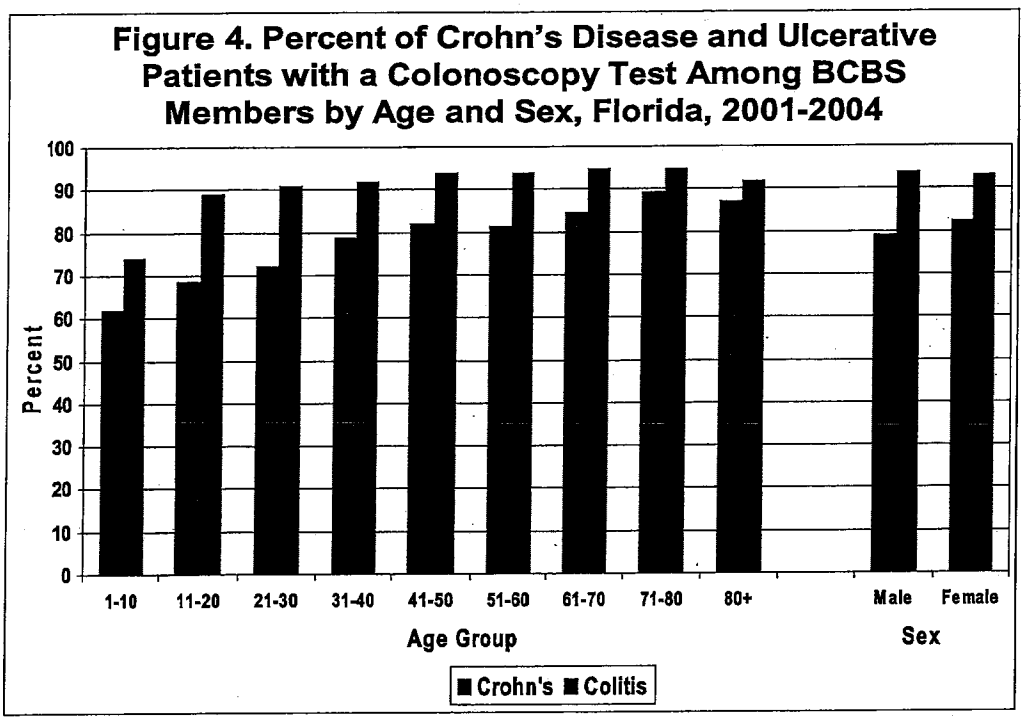
The four-year prevalence was the highest among people between the ages of 71 and 80 years. The prevalence increased by age, except among people age 81 years and older. (Figure 3)

The prevalence was slightly higher among females than among males for Crohn's disease (229 per 100,000 people versus 211 per 100,000 people), and ulcerative colitis (302 per 100,000 people versus 295 per 100,000 people). (Figure 3)

Figure 3. Prevalence of Crohn's Disease and Ulcerative Colitis among BCBS Members By Age and Sex, Florida, 2001-2004



A colonoscopy is a medical procedure that is required to confirm the diagnosis of Crohn's disease and ulcerative colitis. Among BCBS members, a majority of new patients with Crohn's disease and ulcerative colitis had a colonoscopy. The percent of Crohn's disease patients who had a colonoscopy increased by age, from 61 percent among patients under age 11, to 87 percent among patients aged 80 years and older. The percent of patients with a colonoscopy was higher among ulcerative colitis patients than among Crohn's disease patients. Ninety percent of patients with ulcerative colitis had a colonoscopy with the exception of patients under age 11. (Figure 4)



Among Crohn's disease patients, more females (82 percent) had a colonoscopy than did males (79 percent). Among ulcerative colitis patients, 93 percent of both males and females had a colonoscopy.

Among BCBS members, the prevalence of Crohn's disease was greater than 400 per 100,000 in Liberty, Wakulla, Jefferson, Brevard, Glades, and Lee counties. (Figure 5) Liberty, Wakulla, Leon, Columbia, Brevard, Glades, Orange, Hillsborough, Polk, Sarasota, Palm Beach, and Broward counties had a prevalence of ulcerative colitis greater than 400 per 100,000 people. (Figure 6) Liberty, Wakulla, Brevard, and Glades counties had a high prevalence for both Crohn's disease and ulcerative colitis.

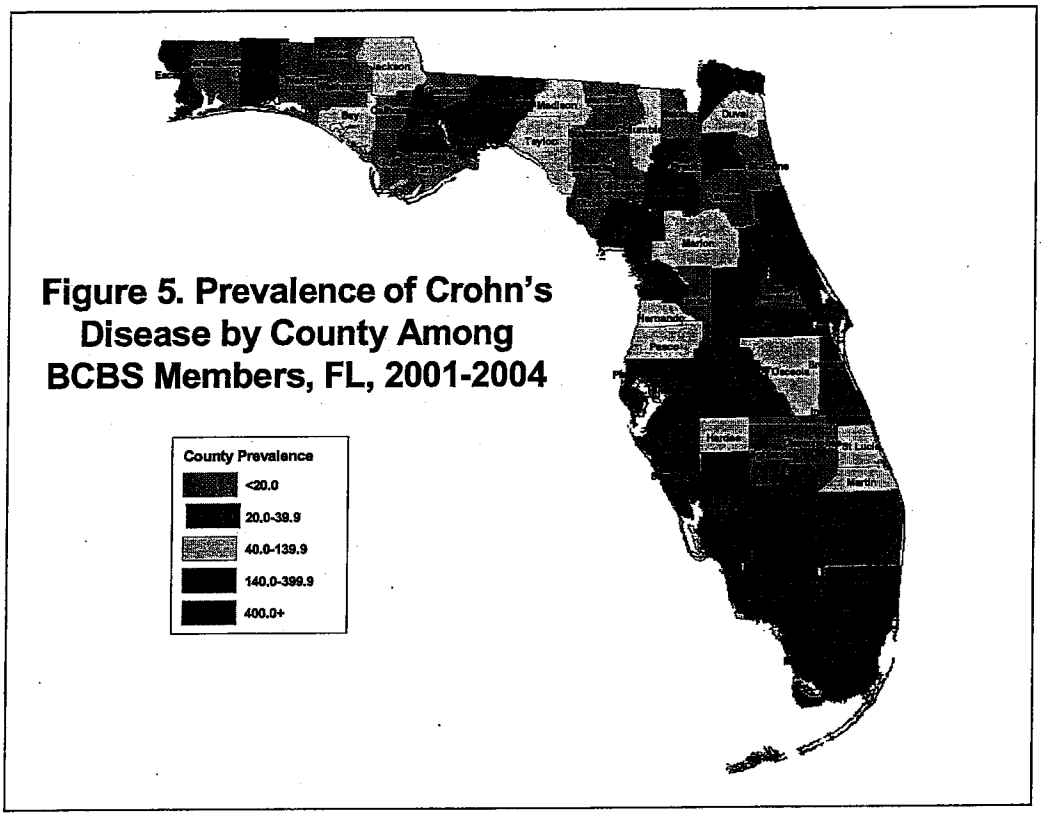


Figure 5. Prevalence of Crohn's Disease by County Among BCBS Members, FL, 2001-2004

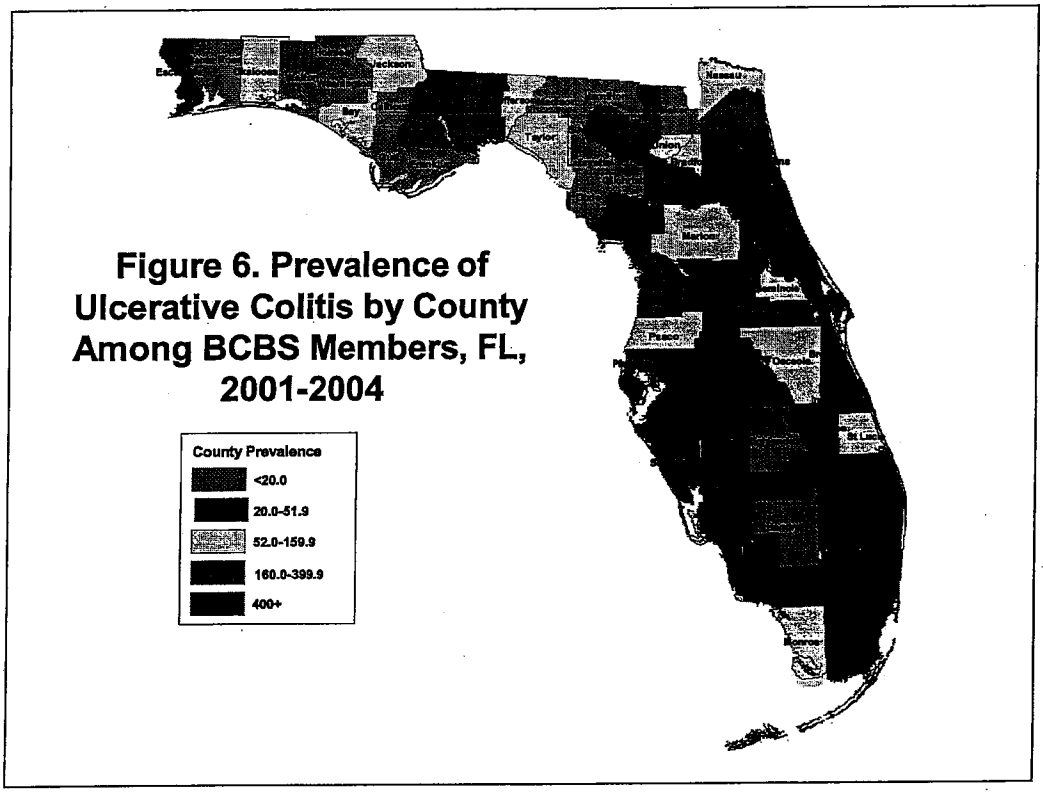


Figure 6. Prevalence of Ulcerative Colitis by County Among BCBS Members, FL, 2001-2004

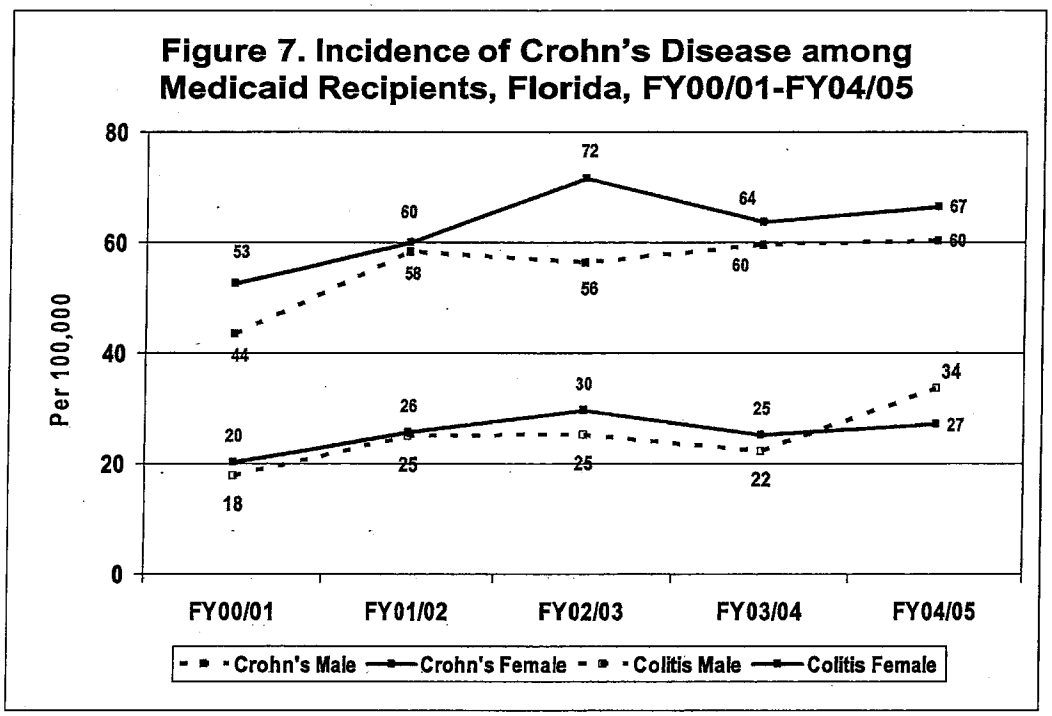
Medicaid data

The number of Medicaid recipients receiving medical service varied greatly during FY 2000-2001 through FY 2004-2005. The average number of recipients with at least one claim for medical service was 1,184,535 per year. The average number of Medicaid recipients diagnosed with Crohn's disease per year was 717 patients, with a prevalence of 61 per 100,000 people. On average, 304 recipients per year were diagnosed with ulcerative colitis, with a prevalence of 26 per 100,000 people. The number of recipients diagnosed with other colitis was 26,055 per year with a prevalence of 2,200 per 100,000 people. (Table 2)

Tables 2. Number of Patients with IBD among Medicaid Recipients, Florida, FY00/01-FY04/05

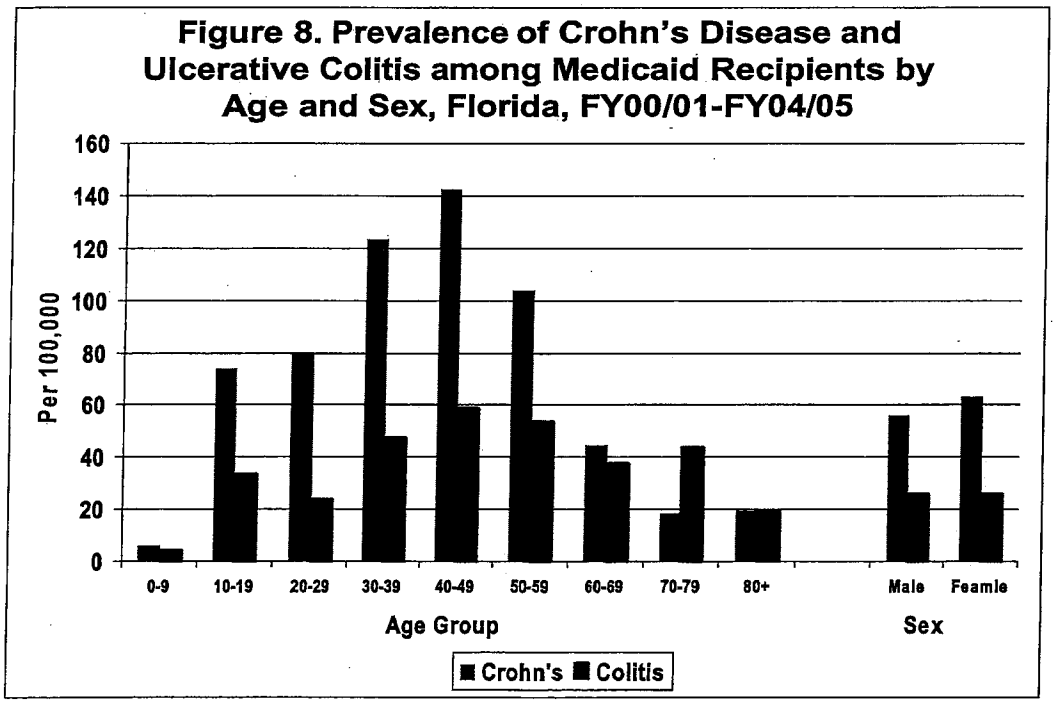
	FY00/01	FY01/2	FY02/3	FY03/4	FY04/5
# of Recipients	**1,042,369**	**1,084,413**	**895,044**	**1,170,599**	**1,730,249**
Crohn's Disease					
Total	**513**	**644**	**590**	**728**	**1,111**
Female	**348**	**416**	**406**	**474**	**733**
Male	**165**	**228**	**184**	**254**	**378**
Ulcerative Colitis					
Total	**202**	**275**	**250**	**283**	**510**
Female	**134**	**177**	**168**	**188**	**300**
Male	**68**	**98**	**82**	**95**	**210**
Other					
Total	**25,966**	**20,785**	**18,755**	**27,360**	**37,411**
Female	**13,863**	**10,990**	**9,928**	**14,317**	**20,076**
Male	**12,101**	**9,793**	**8,824**	**13,038**	**17,333**

The prevalence of both Crohn's disease and ulcerative colitis increased during FY2000-2001 through FY2004-2005. The prevalence of Crohn's disease increased by 30 percent (38 percent for males and 27 percent for females), and the prevalence of ulcerative colitis increased by 52 percent (87 for males and 35 percent for females). (Figure 7)



The age-specific prevalence was the highest among people between ages 40 and 49 for both Crohn's disease (142 per 100,000 persons) and ulcerative colitis (58 per 100,000 persons).

Females had a higher prevalence of Crohn's disease (63 per 100,000 persons) than males (56 per 100,000 persons). However, the prevalence of ulcerative colitis was the same (26 per 100,000 persons) among both males and females. (Figure 8)



Hospital discharge data

There were 12,769,086 patients discharged from hospitals during 1995-2004. During this period, 187,700 patients were diagnosed with IBD, among whom 15,340 had Crohn's disease and 13,820 had ulcerative colitis.

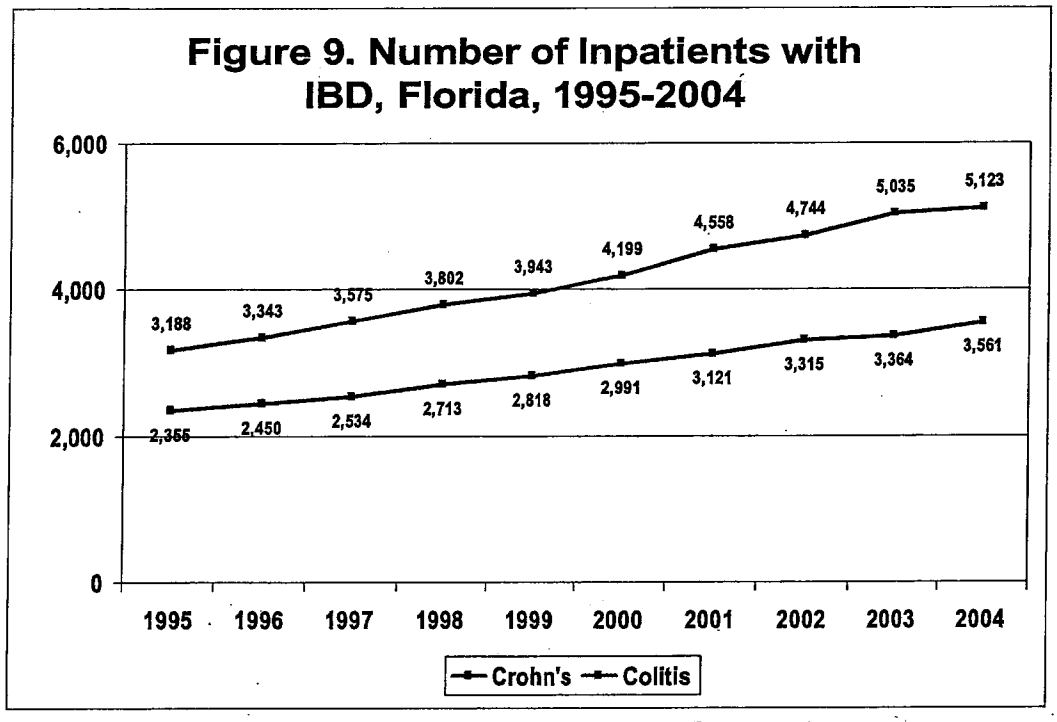
Among patients with Crohn's disease and ulcerative colitis, there were more female patients, than there were male patients. Although most Crohn's disease and ulcerative colitis patients were Whites, many patients of other races/ethnicities were diagnosed with IBD as well. (Table 3)

Table 3. Average Number of New Patients Hospitalized with IBD per Year, Florida, 1995-2004

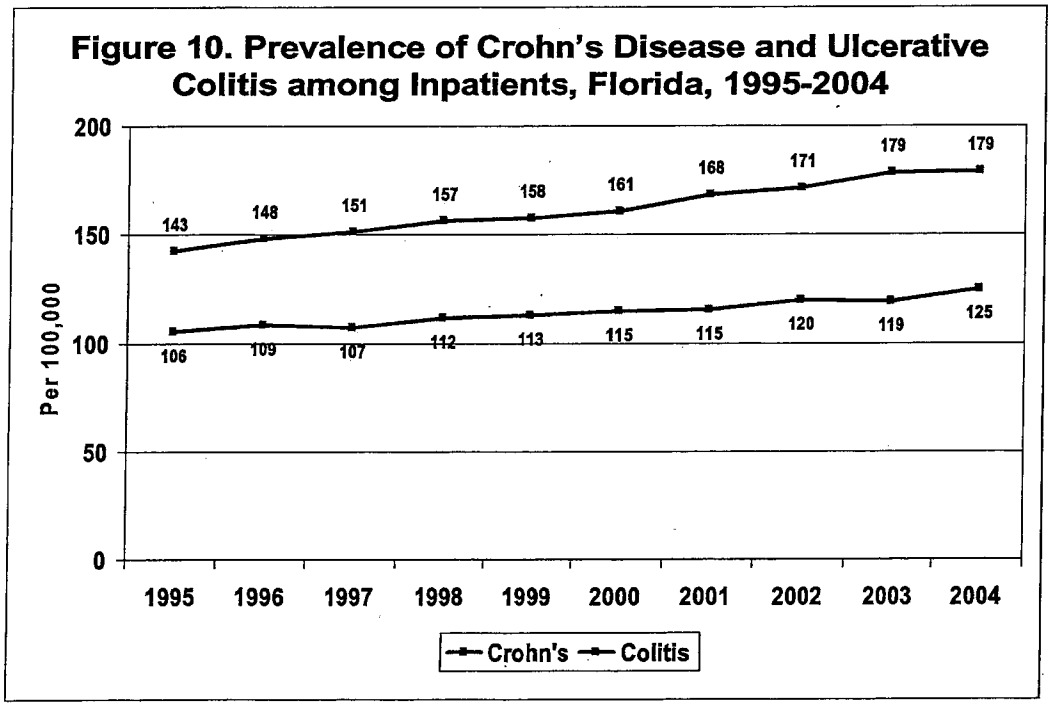
	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	18770	1534	1382	16314					
By Age					By Race				
0-	246	0	0	246	Black	2,186	92	90	2,039
1-10	1,129	5	3	1,123	Hispanic	2,424	90	117	2,256
11-20	534	60	30	456	Other	442	35	34	383
21-30	1,193	158	83	987	White	13,718	1,318	1,140	11,635
31-40	1,946	227	141	1,638	By Insurance				
41-50	2,207	237	152	1,882	No Insurance	1,265	141	72	1,083
51-60	2,156	217	177	1,821	Medicare	8,899	602	741	7,788
61-70	2,708	231	232	2,309	Medicaid	2,120	95	71	1,993
71-80	3,673	260	331	3,172	Private	6,052	646	463	5,090
81+	2,980	139	231	2,681	Other	433	50	35	361
By Sex									
Male	7,134	662	600	6,049					
Female	116,356	872	782	10,265					

New patients, excluding patients who were diagnosed as outpatients

The number of patients with Crohn's disease and ulcerative colitis that were hospitalized increased by 61 percent and 51 percent, respectively, from 1995 to 2004. In 2004, 5,123 Crohn's disease and 3,561 ulcerative colitis patients were hospitalized. (Figure 9)
The 10-year overall prevalence was 120.1 per 100,000 people for Crohn's disease and 108.2 per 100,000 people for ulcerative colitis during the 10-year period. For calculating overall prevalence, a patient with an IBD diagnosis was counted once, regardless of how many times the patient was hospitalized in the 10-year period. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with either Crohn's disease and/or ulcerative colitis was 221.0 per 100,000 people among inpatients.

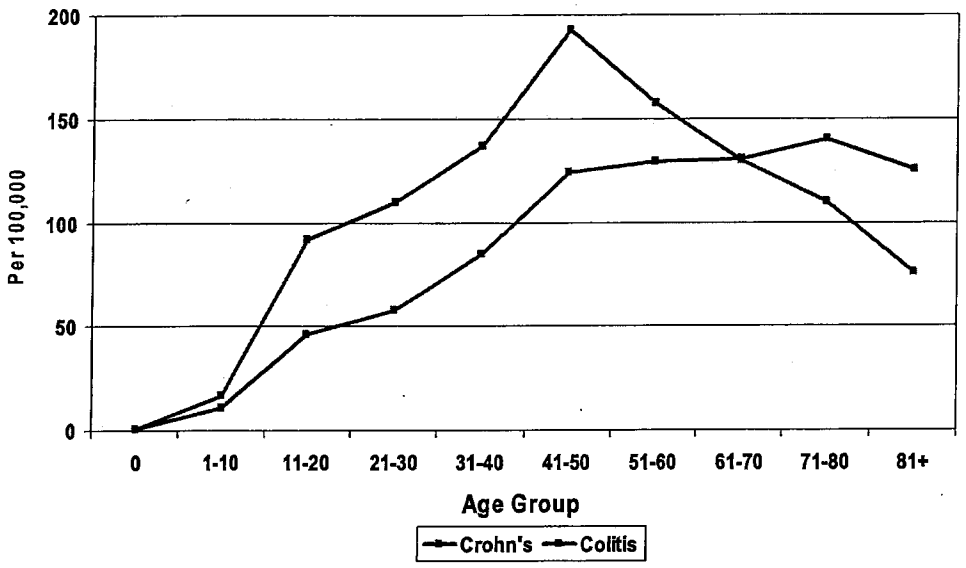


The annual prevalence of Crohn's disease increased by 26 percent, from 143 per 100,000 people in 1995 to 179 per 100,000 people in 2004. The annual prevalence of ulcerative colitis increased by 18 percent, from 106 per 100,000 persons in 1995 to 125 per 100,000 persons in 2004. (Figure 10)



The age-specific prevalence of Crohn's disease increased by age, reached a peak of 193 per 100,000 people among the 41-to-50-year age group, then it decreased to 76 per 100,000 people among people aged 81 years and older. The prevalence of ulcerative colitis also increased by age, reached a peak of 140 per 100,000 people among 41-to-50 year age group, and decreased to 125 per 100,000 people among people aged 81 years and older. (Figure 11)

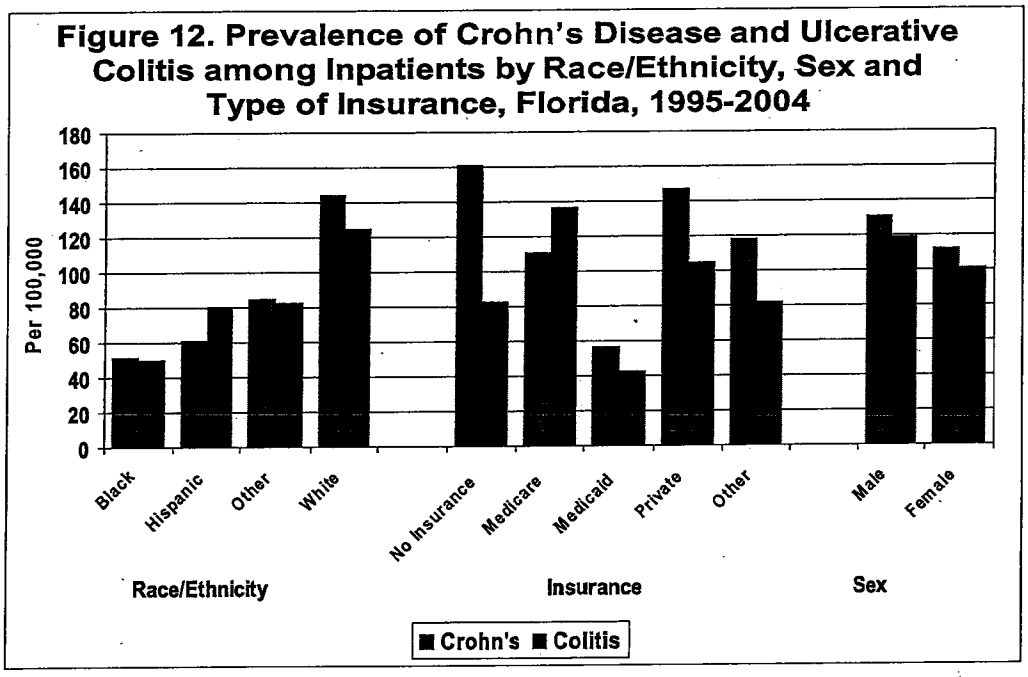
Figure 11. Prevalence of Crohn's Disease and Ulcerative Colitis among Inpatients by Age Group, Florida, 1995-2004



Whites had the highest prevalence of Crohn's disease (145 per 100,000 people) and ulcerative colitis (125 per 100,000 people) among four race/ethnicity groups. Blacks had the lowest prevalence for both Crohn's disease (61 per 100,000 people) and ulcerative colitis (51 per 100,000 people).

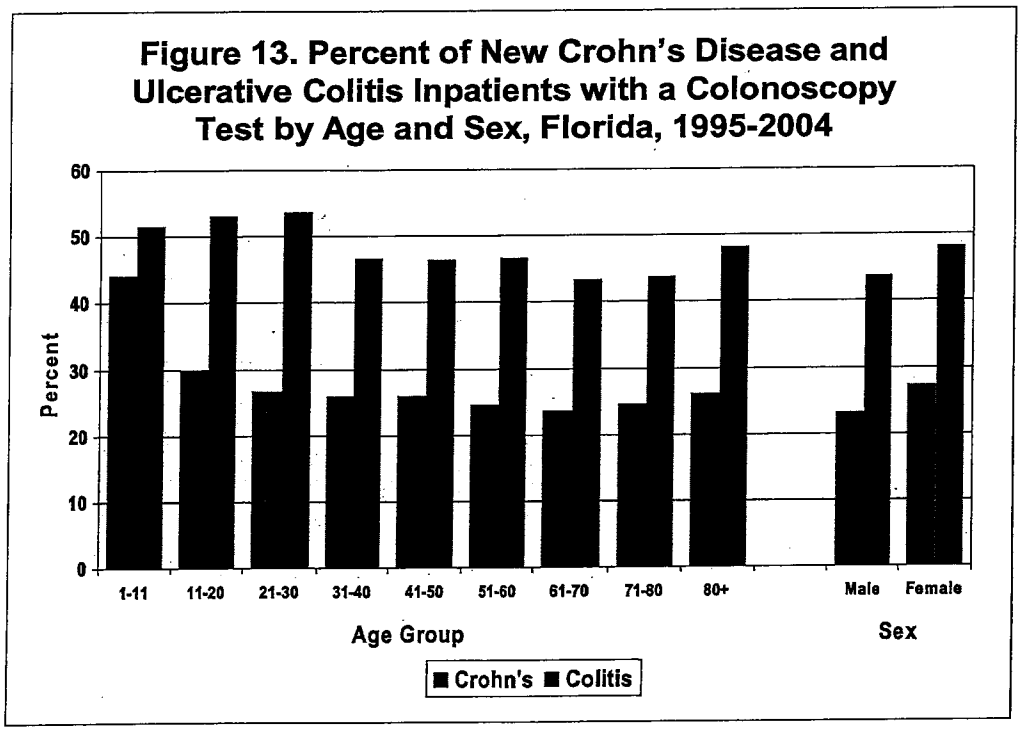
Patients who had a private medical insurance (147 per 100,000 people) and patients without any insurance (162 per 100,000 people) had a higher prevalence for Crohn's disease than their counterparts did. Medicare beneficiaries had the highest prevalence (137 per 100,000 people) of ulcerative colitis. Medicaid recipients had the lowest prevalence of both Crohn's disease (57 per 100,000 people) and ulcerative colitis (43 per 100,000 people).

Males had a higher prevalence of both Crohn's disease (131 per 100,000 people versus 113 per 100,000 people) and ulcerative colitis (119 per 100,000 people versus 101 per 100,000 people) than females. (Figure 12)



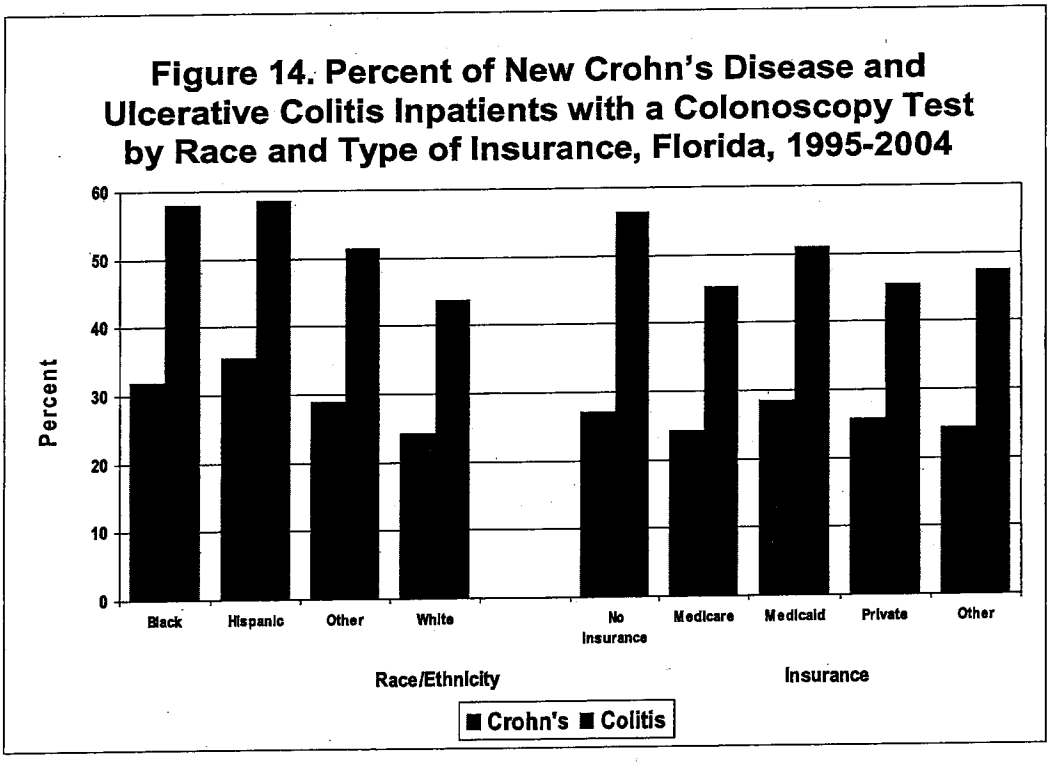
Approximately one quarter (25.5 percent) of new Crohn's disease patients had a colonoscopy. The percent of patients with a colonoscopy was higher among younger patients (under age 20) than among older patients, and higher among females than among males.

Among new patients with ulcerative colitis, 42.3 percent had a colonoscopy. The percent of patients with a colonoscopy was also higher among patients under age 30 and among females than among their counterparts. (Figure 13)

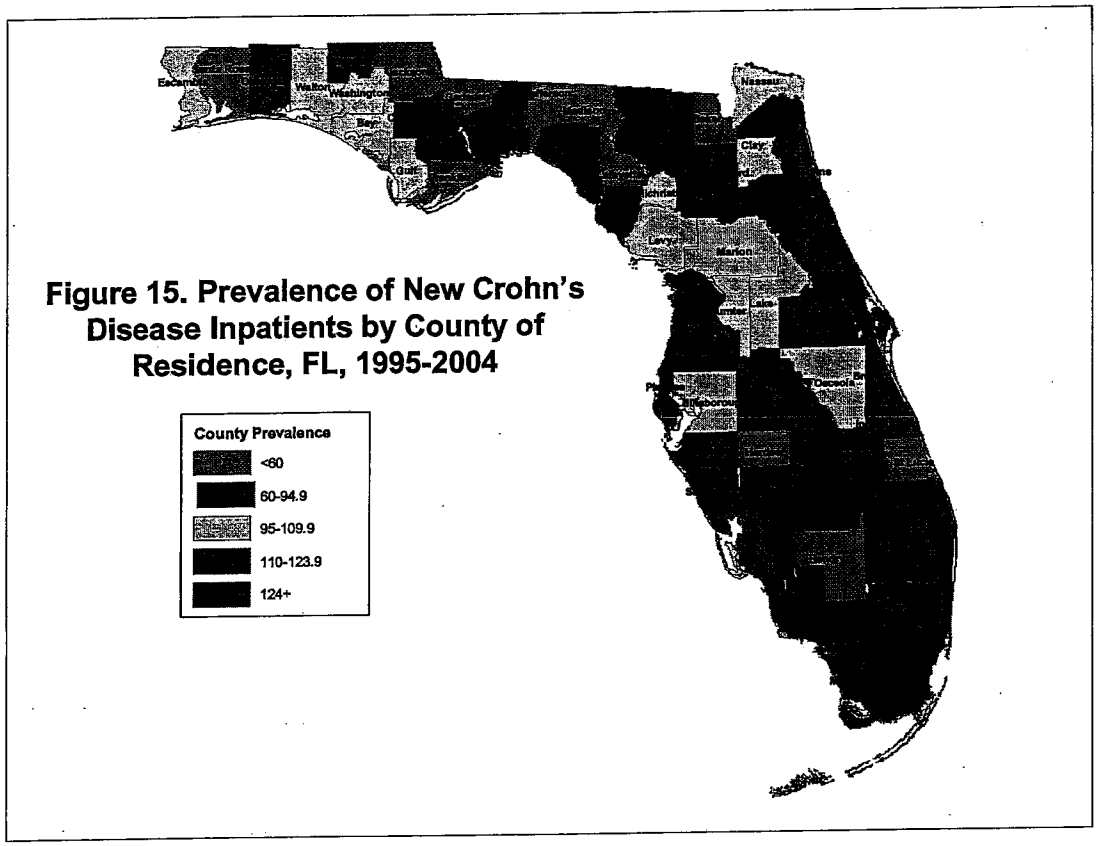


The percent of new Crohn's disease patients with a colonoscopy was the highest among Hispanics. Both Medicaid recipients and patients without any medical insurance had a higher percent than their counterparts did. The percent of new ulcerative colitis patients with a colonoscopy was higher among Hispanics and Blacks than Whites and people of other races. The percent of ulcerative colitis patients with a colonoscopy was also higher among people without medical insurance and Medicaid recipients than for people with a private insurance and Medicare beneficiaries. (Figure 14)

Figure 14. Percent of New Crohn's Disease and Ulcerative Colitis Inpatients with a Colonoscopy Test by Race and Type of Insurance, Florida, 1995-2004



Twelve counties had a 10-year overall prevalence of Crohn's disease of 124 per 100,000 people or greater in Florida. These counties are Holmes, Union, Seminole, Hernando, Pasco, Pinellas, Indian River, Okeechobee, Sarasota, Charlotte, Collier, and Monroe. (Figure 15)



Twelve counties had a prevalence of ulcerative colitis of 130 per 100,000 or greater in Florida. These counties are Gulf, Suwannee, Columbia, Union, Citrus, Sumter, Lake, Hernando, Osceola, Sarasota, Charlotte, and Collier. (Figure 16)

Union, Hernando, Sarasota, Charlotte, and Collier had higher prevalence rates for both Crohn's disease and ulcerative colitis than other counties in Florida during 1995-2004.

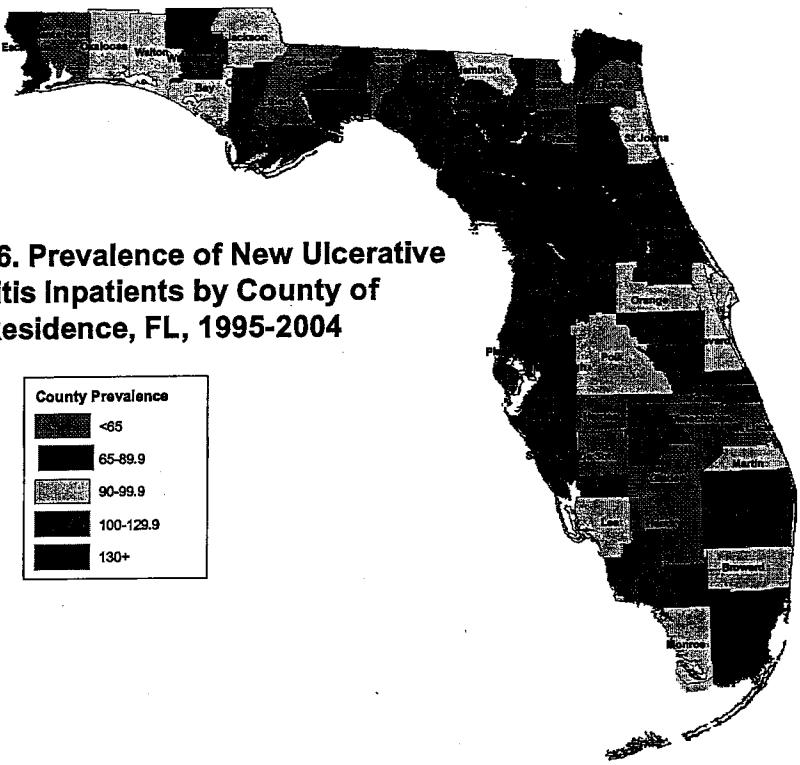


Figure 16. Prevalence of New Ulcerative Colitis Inpatients by County of Residence, FL, 1995-2004

Ambulatory patient data

There were 12,710,291 patients who received at least one ambulatory care service during 1997-2004. Among these patients, 22,005 were diagnosed with Crohn's disease, 32,541 were diagnosed with ulcerative colitis, and 120,138 were diagnosed with other colitis.

There were more females than males among patients with Crohn's disease and ulcerative colitis. Approximately 80 percent of Crohn's disease and ulcerative colitis patients were White, and 60 percent of patients had a private health insurance. (Table 4)

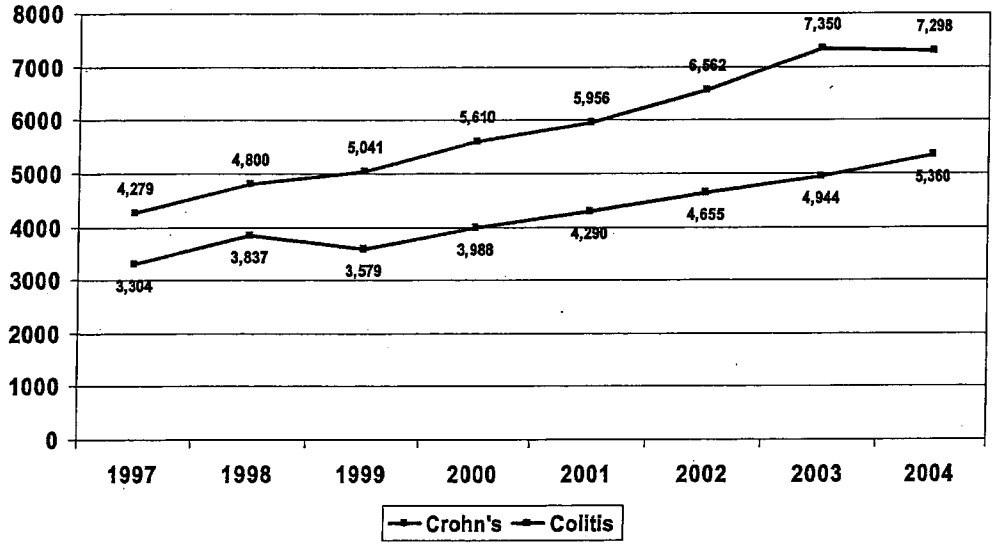
Table 4. Average Number of New Outpatients with IBD per Year, Florida, 1997-2004

	All IBD	Crohn's	Colitis	Other		All IBD	Crohn's	Colitis	Other
Total	20,143	2,751	4,068	15,017					
By Age					By Race				
0-	28	1	3	27	Black	950	111	186	729
1-10	123	11	11	105	Hispanic	1,492	142	268	1,196
11-20	503	135	115	314	Other	1,583	292	382	1,007
21-30	1,323	300	327	837	Whites	16,117	2,207	3,232	12,085
31-40	2,374	439	595	1,588	By Insurance				
41-50	3,185	498	707	2,284	No Insurance	509	77	100	366
51-60	3,697	494	706	2,803	Medicare	7,337	756	1,291	5,815
61-70	3,836	423	710	2,992	Medicaid	629	91	88	490
71-80	3,768	348	679	3,004	Private	11,100	1,726	2,446	7982
81+	1,306	105	218	1,064	Other	568	101	142	363
By Sex									
Male	8,151	1,180	1,915	5,829					
Female	11,993	1,571	2,153	9,189					

New patients, including patients who were also hospitalized

The number of Crohn's disease patients that were treated as ambulatory patients was 3,304 in 1997 and increased by 62 percent to 5,360 in 2004. The number of ulcerative colitis patients increased by 71 percent, from 4,279 in 1997 to 7,298 in 2004. (Figure 17)

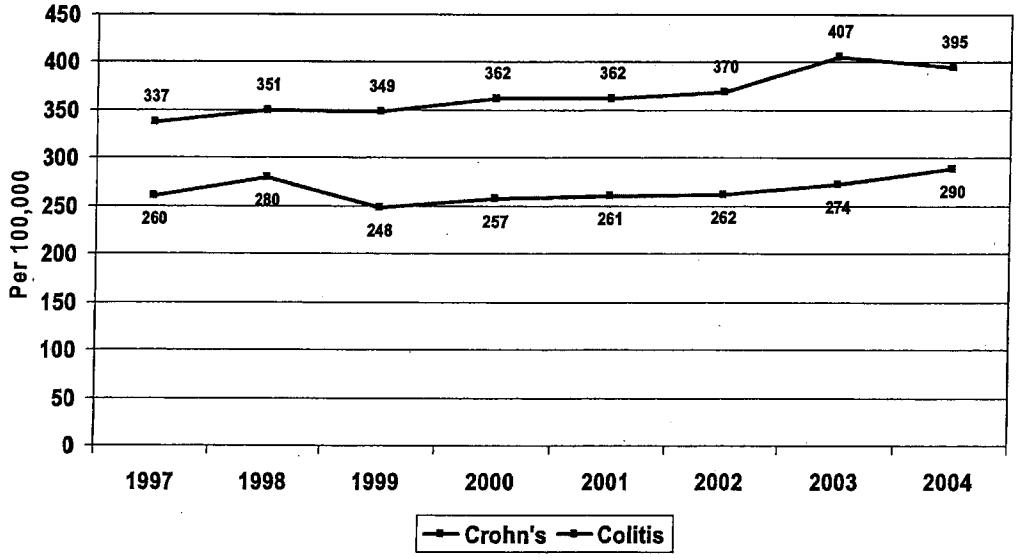
Figure 17. Number of Outpatients with Crohn's Disease and Ulcerative Colitis, Florida, 1997-2004



The 8-year overall prevalence (each patient was counted only once) was 173.1 per 100,000 people for Crohn's disease and 256 per 100,000 people for ulcerative colitis during 1997-2004. Some patients were diagnosed with both Crohn's disease and ulcerative colitis. The average prevalence of patients with Crohn's disease and/or ulcerative colitis was 412.4 per 100,000 people.

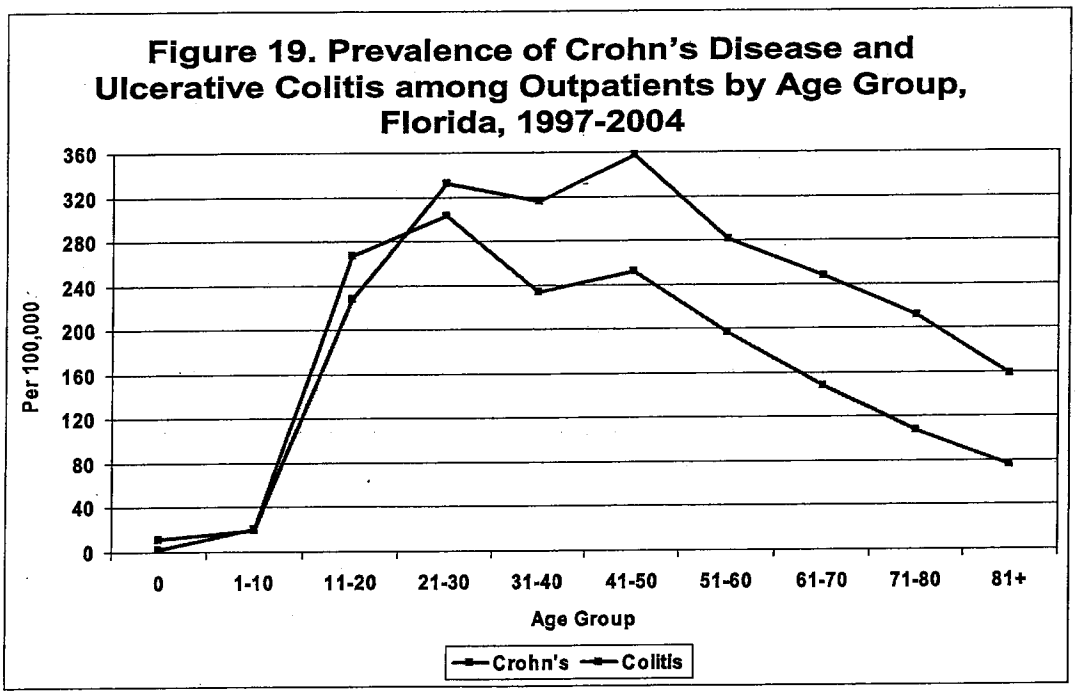
The annual prevalence of ambulatory patients increased for both Crohn's disease and ulcerative colitis in the 8-year period. The prevalence of Crohn's disease increased by 11 percent, from 260 per 100,000 persons in 1997 to 289 per 100,000 persons in 2004. The prevalence of ulcerative colitis increased by 17 percent, from 337 per 100,000 persons in 1997 to 395 per 100,000 persons in 2004. (Figure 18)

Figure 18. Prevalence of Outpatients with Crohn's Disease and Ulcerative Colitis, Florida, 1997-2004

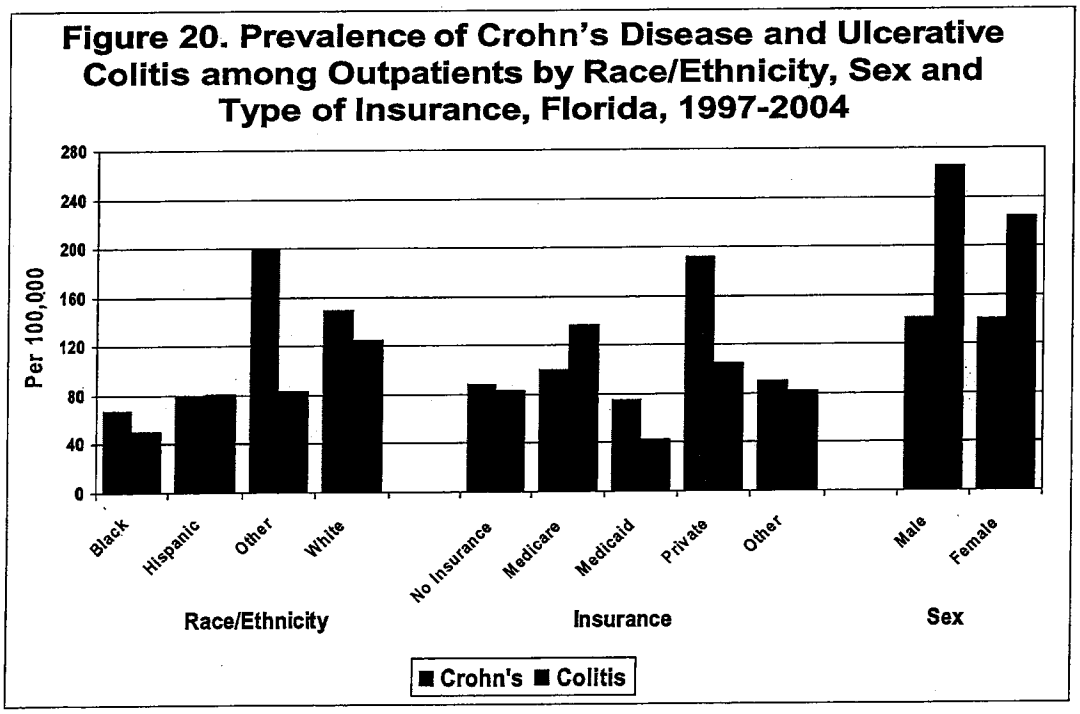


The age-specific prevalence of Crohn's disease increased dramatically in teenagers and peaked in the 21- to 30-year-old age group. Age-specific prevalence decreased among patients aged 30 years and older, with an exception of an increase in the 41- to 50-year-old age group.

The age-specific prevalence of ulcerative colitis increased among patients between ages 11 and 30 years, and then reached a peak of 358 per 100,000 persons among the 41- to 50-year–old age group. The prevalence then decreased by age among people aged 50 years and older. (Figure 19)



Patients of other races had the highest prevalence of Crohn's disease at 200 per 100,000 people. The prevalence of Crohn's disease among Whites was the second highest at 150 per 100,000 people. The prevalence of Crohn's disease was the highest among patients with a private health insurance (193 per 100,000 people). The prevalence was the lowest among Medicaid recipients (75 per 100,000 people). The prevalence of Crohn's disease was slightly higher among males (143 per 100,000 people) than among females (141 per 100,000 people). (Figure 20)

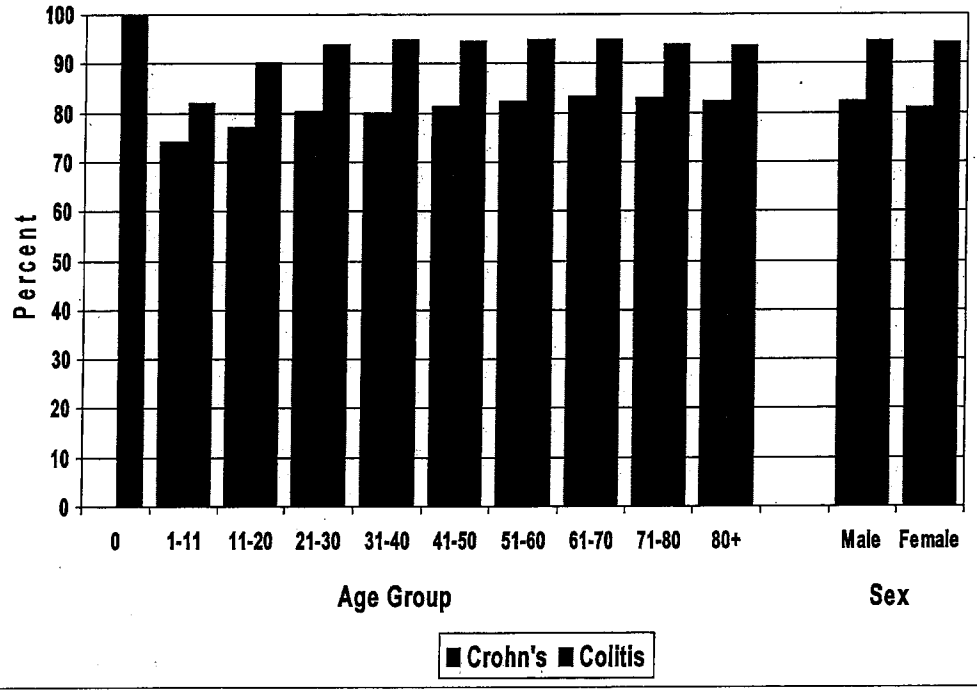


The prevalence of ulcerative colitis was the highest among Whites (125 per 100,000 people), and among Medicare beneficiaries (137 per 100,000 people). The prevalence was the lowest among Medicaid recipients (43 per 100,000 people). Males had a higher prevalence of ulcerative colitis (265 per 100,000 people) than females (224 per 100,000 people). (Figure 22)

Approximately 82 percent of Crohn's disease patients had a colonoscopy. The percent of Crohn's disease patients with a colonoscopy was lower among patients under age 20 than among older patients. The percent was the same among both males and females.

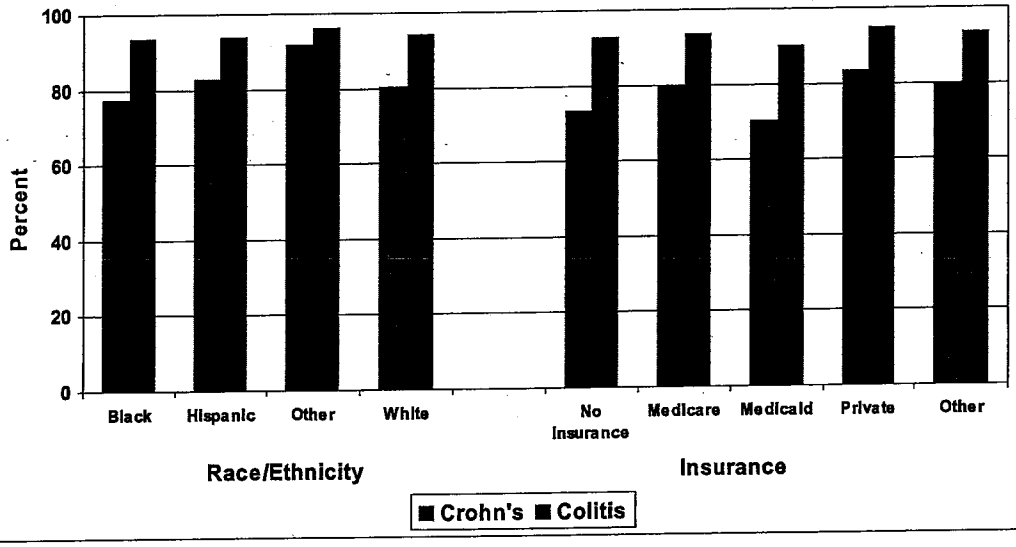
A majority (94 percent) of ulcerative colitis patients had a colonoscopy. The percent of ulcerative colitis patients with a colonoscopy was higher among patients aged 20 years and older. There was no difference in the percentage between males and females. (Figure 21)

Figure 21. Percent of New Crohn's Disease and Ulcerative Colitis Outpatients with a Colonoscopy Test by Age and Sex, Florida, 1997-2004



The percent of Crohn's disease patients with a colonoscopy was the highest among patients of other races (96 percent), and among patients with a private health insurance (95 percent). The percent of ulcerative colitis patients who had a colonoscopy was the lowest among Medicaid recipients (90 percent). (Figure 22)

Figure 22. Percent of New Crohn's Disease and Ulcerative Colitis Outpatients with a Colonoscopy Test by Race/Ethnicity and Type of Insurance, Florida, 1997-2004



Twelve counties had an eight-year overall prevalence of Crohn's disease of 140 per 100,000 persons or greater in Florida. These counties are Columbia, Union, Clay, Alachua, Flagler, Seminole, Pinellas, Manatee, Sarasota, Lee, Hendry, and Broward. (Figure 23) It is noteworthy that Union, Seminole, Pinellas, and Sarasota also had a high prevalence of Crohn's disease among inpatients. (Figure 15)

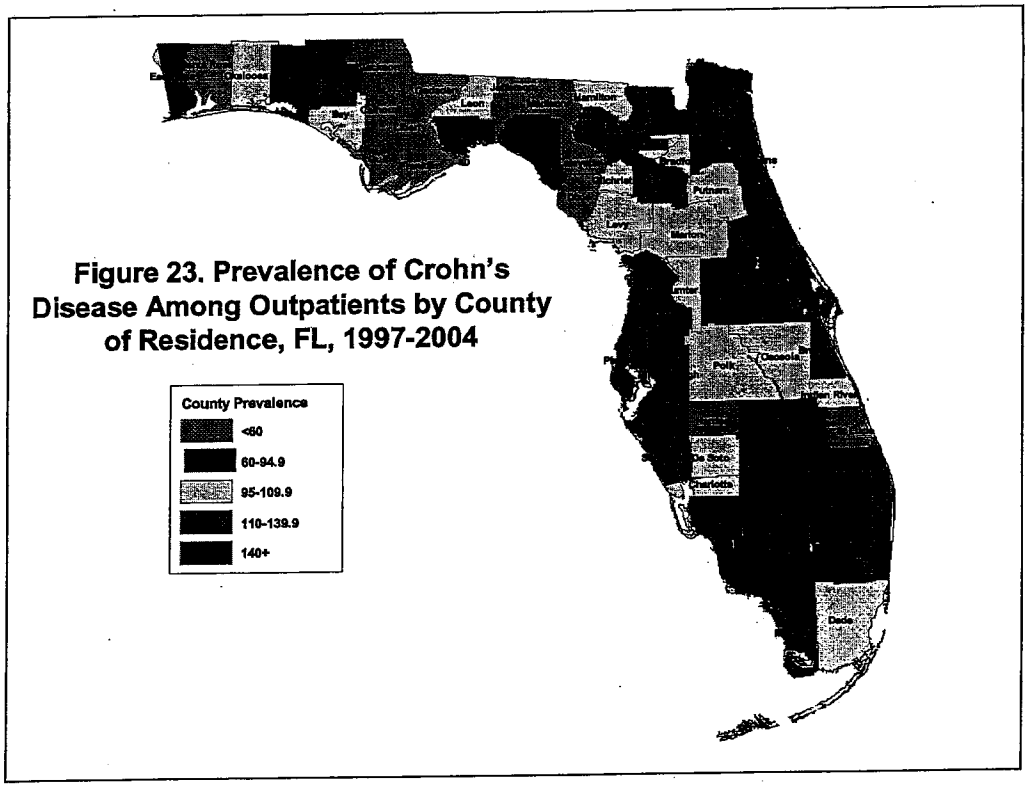


Figure 23. Prevalence of Crohn's Disease Among Outpatients by County of Residence, FL, 1997-2004

Thirteen counties had an overall prevalence of ulcerative colitis of 300 per 100,000 people or greater in Florida. These counties are Gulf, Leon, Jefferson, Citrus, Lake, Hernando, Seminole, Pinellas, Sarasota, Collier, Palm Beach, Broward, and Monroe. (Figure 24) Among these counties, Gulf, Citrus, Lake, Hernando, Sarasota, and Collier also had a high prevalence of hospitalization for ulcerative colitis.

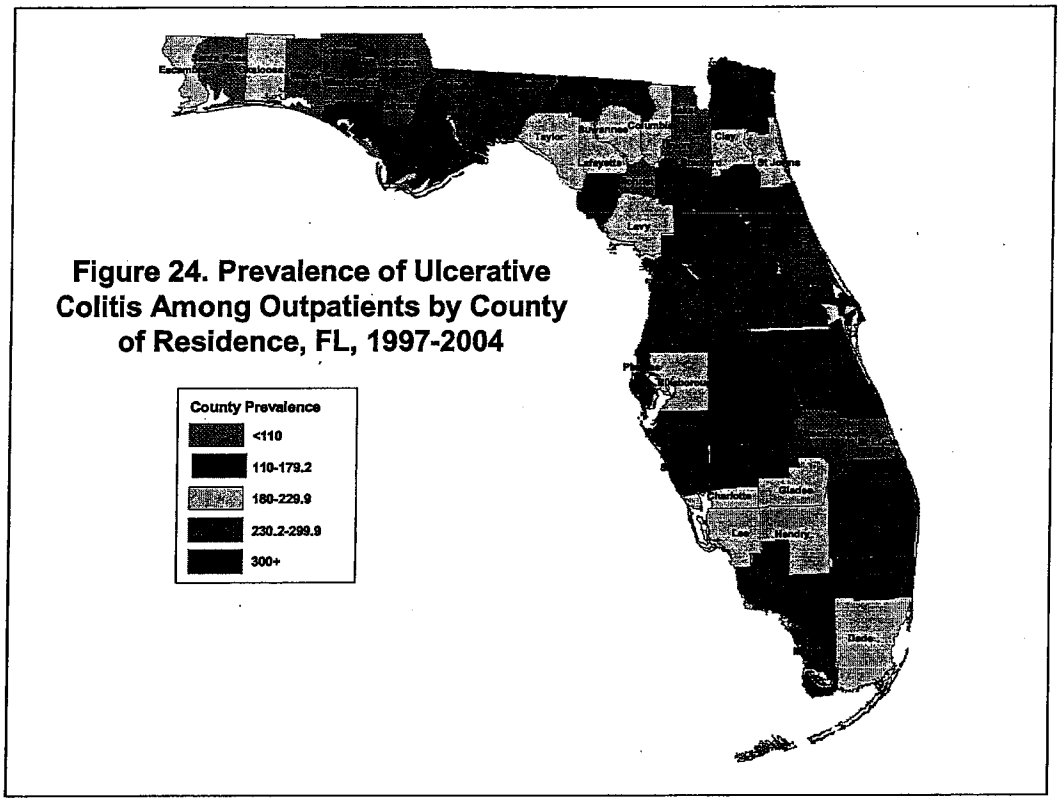


Figure 24. Prevalence of Ulcerative Colitis Among Outpatients by County of Residence, FL, 1997-2004

Seminole, Pinellas, Sarasota, and Broward counties had high prevalence rates for both Crohn's disease and ulcerative colitis among ambulatory patients.

Sarasota was the only county that had a high prevalence for both Crohn's disease and ulcerative colitis among both inpatients and ambulatory patients.

BRFSS Survey

A total of 1,678 respondents answered the survey questions in the IBD module. Excluded from the analysis were 19 respondents who answered "don't know" or "not sure." Among the 1,659 respondents included in the final analysis, 63 reported that someone in their household was diagnosed with IBD. Three (4.8 percent) of 63 households had more than one person diagnosed with IBD.

BRFSS data suggested that 3.2 percent of all households have IBD patient(s), with 4.2 percent of households among Whites, 3.4 percent of households among Hispanics, 1.6 percent of households among Blacks, and 1.7 percent of households among other races.

There was no difference in the percent of having somebody with IBD between households with annual income less than $50,000 and household with annual income of $50,000 or more.

Among the 3,066 adults and 916 children within the 1,659 households, 66 persons were reported being diagnosed with IBD. Because the BRFSS survey did not ask for the age of individuals with IBD, the DOH team estimated that two of the people with IBD were children (under age 20), based on the age distribution of hospital discharge, and ambulatory care, data. The prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. These estimates were not weighted prevalence, which did not take into account of probability of survey respondents being included in the survey. A weighted prevalence will be available after CDC has completed the data weighting process.

Among survey respondents, 12 (18.2 percent) persons with IBD in 10 households were hospitalized in the past year. There was no difference in the percent of households with an IBD patient being hospitalized by race or by household income.

GI Physician Survey

The DOH received 113 completed survey questionnaires from GI physicians. The GI physicians who responded to the survey reported that 9,005 (7.3 percent) IBD patients were seen in the past 12 months among their 123,480 patients within that timeframe. Among IBD patients, approximately 14.2 percent were diagnosed in the past 12 months.

It was estimated that 40 percent of IBD patients were between the ages 20 and 45 years, and 30 percent were between the ages 45 and 65 years. IBD patients under age 20 years only accounted for approximately 10 percent.

Whites accounted for 93 percent of IBD patients; Blacks accounted for approximately 5 percent. Very few IBD patients were either Asian or other races.

Among IBD patients, females accounted for 51 percent and males for 49 percent. Approximately one quarter (22.4 percent) of patients had a family history of IBD, and one-eighth (12.2 percent) were hospitalized in the past 12 months.

The majority (94 percent) of IBD patients under the care of the responding physicians were enrolled in colon cancer surveillance.

IBD Patient Survey

The DOH received 27 completed survey questionnaires from IBD patients who voluntarily participated in the survey. The following are the results of the survey:

Age range of participants: 9 to 79 years

Age of diagnosis:

Age	<10	11-19	20-39	40-64	65 +
Percent	7.5	11	48	26	7.5

Average time living with IBD: 11.1 years

Gender: 78 percent Female 22 percent Male

Race/ethnicity: 96 percent Caucasian 4 percent Other

Jewish Decent: 33 percent yes, 63 percent no, and 4 percent unsure

Region of birth (within the US):
93 percent of respondents were born in the United States, of those:

Region	Southeast	Midwest	Northeast
Percent	28	4	68

Type of IBD:

Disease	Crohn's	Colitis	Crohn's & Colitis
Percent	56	40	4

Severity of symptoms:
78 percent of respondents reported their illness as active, of those:

Severity	Mild	Moderate	Severe
Percent	33	62	5

Family History:- 18 percent had a family history; 78 percent reported no family history of IBD; and 4 percent unsure

Proximity to cattle:
- 19 percent lived near cattle prior to diagnosis.

Smoking status:
- 30 percent of respondents were current smokers, and 67 percent lived with a smoker prior to diagnosis. The percent of current smoking among IBD patients was higher than the 2004 state average prevalence (20.2 percent).

Colonoscopy:
- 56 percent had first colonoscopy due to IBD symptoms

Other medical conditions prior to diagnosis of IBD:
- 27 percent had serious medical illnesses
- 11 percent had psychological illnesses
- 37 percent were hospitalized
- 59 percent reported having surgeries

Of those reporting surgeries:
- 25.0 percent had appendectomies; 62.5 percent had tonsillectomies; 12.5 percent had other surgeries
- Other surgeries listed: liver transplant and c-section

Assessment of overall health:

- 18 percent said their health was poor

CONCLUSIONS

The Crohn's disease and ulcerative colitis epidemiologic study was conducted by the DOH in conjunction with the University of Florida, AHCA, and BCBS, under the guidance of the Advisory Committee. This study is a large population-based study that combined multiple sources of data that covers a majority of Florida's population. The data used in this study included 42,372,600 patient claim records in up to 10 years and survey data of approximately 2,000 households, providers, and patients.

This study was the first to provide state-specific data on IBD for Florida, in terms of estimating the prevalence of Crohn's disease and ulcerative colitis, the demographic characteristics of IBD patients, and major risk factors of the IBD.

Estimated prevalence of Crohn's disease and ulcerative colitis

The Prevalence

The population-based prevalence of Crohn's disease is estimated at 222 per 100,000 people, and the prevalence of ulcerative colitis at 307 per 100,000 people. These estimates were calculated based on age distribution of Florida's population and age-specific prevalence of Crohn's disease and ulcerative colitis of BCBS members.

The BCBS data showed that the prevalence of IBD among BCBS members, including inpatients and outpatients was for:

- Crohn's disease: 220 per 100,000 persons
- Ulcerative colitis: 300 per 100,000 persons
- Other colitis: 520 per 100,000 persons

BCBS data captured information on both hospitalizations (severe disease) and clinic visits (less severe disease). BCBS data were a good source in determining the prevalence of IBD because there is less disparity in access to health care among BCBS members. However, BCBS members are not a representative sample for overall Florida population, among which approximately 17 percent of people without a health insurance.

The estimates based on BCBS data were consistent with findings from previous epidemiologic studies in North America, which suggested population-based prevalence varied from 162 per 100,000 people to 199 per 100,000 people for Crohn's disease and from 170 per 100,000 people to 246 per 100,000 people.

The combined hospital discharge data and ambulatory patient data showed that, among patients treated in hospitals, the prevalence of:

- Any IBD: 2,737.8 per 100,000 people (or 2.74 percent)
- Crohn's disease and/or ulcerative colitis: 633.4 per 100,000 people
- Crohn's disease: 293.3 per 100,000 people
- Ulcerative colitis: 364.2 per 100,000 people

The prevalence of Crohn's disease and ulcerative colitis among inpatients and ambulatory patients was 32 percent and 19 percent, respectively, higher than the prevalence among BCBS members. The difference in prevalence might reflect a compositional difference of populations between hospital patients and BCBS members.

The prevalence of IBD among Medicaid recipients was lower than that among BCBS members the prevalence of patients with:

- Crohn's disease: 61 per 100,000 people.
- Ulcerative colitis: 26 per 100,000 people.
- Other colitis: 2,200 per 100,000 people.

The causes of low prevalence of IBD among Medicaid recipients were unknown based on the data of this study. More studies are needed to examine further the contribution factors of low prevalence of IBD, including access to health care and composition of the Medicaid population.

The BRFSS survey was unable to distinguish type of IBD due to the nature of a telephone survey of the general public. An overall prevalence of IBD was estimated as 2.1 percent for adults and 0.22 percent for children. The BRFSS data represented population-based estimates, although the estimate was un-weighted and might carry large sample errors due to small sample size. The estimate was in line with other data in this study.

Number of Patients

It is estimated that approximately 35,500 Floridians have Crohn's disease and 49,000 have ulcerative colitis based on the estimated prevalence.

Hospitals in Florida served approximately 4,285 Crohn's disease patients and 5,450 ulcerative colitis patients either as inpatients or as ambulatory patients every year, accounting for approximately 12 percent and 11 percent of Crohn's disease and ulcerative colitis patients, respectively.

Demographic Characteristics

Age

The prevalence of Crohn's disease was relatively low among children and the elderly (age 70 years and older). The majority of IBD patients were diagnosed between the ages 11 and 40. The prevalence increased with age until age 50, then decreased with age.

The age-distribution might vary by population depending on the source of data. For example, the age-specific prevalence of ulcerative colitis among Medicaid recipients began to decrease among people age 50 years and older, which might reflect the fact that most Medicaid recipients were under age 50. On the other hand, the age-specific prevalence did not decrease until age 80 and older among hospital inpatients, among whom there were more elderly.

Sex:

The overall prevalence was very close between males and females, with a slightly higher prevalence among females than among males.

Both BCBS and Medicaid are population-based data that show a slightly higher prevalence of IBD among females than among males. However, the prevalence was slightly higher among males than among females for patients seen in hospitals, which might be due to the sex-distribution of hospital patients (more male patients than female patients are seen in hospitals).

Race/ethnicity:

Non-Hispanic Whites had a higher prevalence than non-Hispanic Blacks, Hispanics, and people of other races. Crohn's disease and ulcerative colitis occurred in all racial/ethnic groups.

Household Income:
No difference in prevalence by household income was found according to data from the BRFSS survey.

Type of Health Insurance:
Patients who were Medicare beneficiaries or who had private insurance had a higher prevalence rate of Crohn's disease or ulcerative colitis. Medicaid recipients had the lowest prevalence for both Crohn's disease and ulcerative colitis.

Type of medical insurance was the only variable available in the claim data and might be a surrogate indicator of socioeconomic status. The difference in prevalence might be attributable to the disparity in access to health care and the difference in race and age composition of the populations.

Residential County:
Based on hospital discharge data and ambulatory patient data, the following counties had high prevalence rates:

- Pinellas, Sarasota, and Seminole had a high prevalence of Crohn's disease.
- Citrus, Collier, Gulf, Hernando, Lake, and Sarasota had a high prevalence of ulcerative colitis.

Among BCBS members, those who resided in Glades and Wakulla counties had a high prevalence of Crohn's disease, and those who resided in Wakulla and Liberty counties had a high prevalence of ulcerative colitis.

Sarasota and Palm Beach counties were the only two counties that had a high prevalence of Crohn's disease and ulcerative colitis in all hospital discharge data, ambulatory patient data, and BCBS data.

Risk factors

Previous epidemiologic studies on risk factors of Crohn's disease and ulcerative colitis suggested that although genetic factors might be strongly associated with IBD, environmental factors would explain most variations in the prevalence of IBD. The data in this study supported the findings from previous studies.

Genetic factors

A family history was found among approximately 20 percent of patients from the patient survey, physician survey, and BRFSS survey. Both claim data and survey data indicated that the majority of patients were non-Hispanic White. The patient survey data showed that nearly two thirds of IBD patients were born in the Northeast region of the U.S. and many of IBD patients were of Jewish descent.

The consistency of the finding of family history across surveys and aggregation of IBD in a population indicated a strong association between genetic factors and occurrence of IBD.

Environmental factors

Previous studies suggested several environmental risk factors, including cigarette smoking, consumption of milk, contact with cattle, and receiving certain types of surgery, might be associated with IBD. However, none of these environmental risk factors has been confirmed.

In this study, the DOH surveyed a small group of IBD patients for these potential risk factors. The survey found that the prevalence of cigarette smoking was higher than the state's average prevalence. Many patients were exposed to second-hand smoke, and had surgical procedures, such as tonsillectomy and appendectomy. However, because of the nature of the survey (a self-reported survey without a control group) and small sample size of the survey, no causal relationship could be established between these risk factors and IBD.

Recommendations for Future Studies

This study collected a great deal of data about IBD, and laid a foundation for future studies about IBD in Florida. To better assess IBD and to serve IBD patients in Florida, more studies are needed to:

- Increase sample size for the BRFSS survey to obtain a more accurate estimate of the population-based prevalence of IBD.
- Conduct a case-control study to identify risk factors of IBD.
- Develop an IBD patient voluntary registry through healthcare providers. This registry will provide data for a longitudinal follow-up study of IBD patients and many other studies on treatment, outcome, and patient's quality of life.

ATTACHMENTS

Attachment 1: GI PHYSICIAN SURVEY

A Survey about Inflammatory Bowel Disease Patients

The purpose of this survey is to collect data on inflammatory bowel disease patients, particularly for those who may not have been hospitalized. **All data collected from this survey will be kept strictly confidential.** Please give your best approximation for the following questions.

1. How many patients have you seen in the past 12 months? (please check one)
   □ <100 □ 100-499 □ 500-999 □ 1000-1499 □ 1500 and more

How many of your patients are diagnosed with an Inflammatory Bowel Disease, such as Crohn's disease or ulcerative colitis? ____ ____

2. Please **estimate** the number of IBD patients from question 2 for the following:

Age	<20 yrs	20-44 yrs	45-64 yrs	65 yrs and older
# Patients				

Race	White	Black	Asian	Other
# Patients				

Sex	Male	Female
# Patients		

Ethnicity	Hispanic	Non-Hispanic
# Patients		

3. Among those IBD patients, how many have been hospitalized for IBD in the past 12 months?
   ____ ____

4. How many of your patients with IBD report a family history of the illness?
   ____ ____

5. Among all IBD patients, about how many were diagnosed within the past 12 months?
   ____ ____

6. Do you enter your IBD patients into the colon cancer surveillance program?
   ____yes____no

7. Please provide any additional information or comments about your IBD patients:

_____

_____

_____

Thank you very much for completing the survey. Your information will greatly assist our study. In case we need to contact you for further information, please provide the following information:

Your name: _____
Your office phone number: ( ) _____-_____

Attachment 2: IBD PATIENT SURVEY

Inflammatory Bowel Disease Patient Questionnaire

Dear Respondent: As you may be aware, the Florida Department of Health is conducting a study to uncover the potential role of genetic and environmental risk factors associated with Inflammatory Bowel Disease (as mandated by House Bill 869, also known as the "Crohn's & Colitis Disease Research Act"). This is a short survey designed to evaluate potential genetic and environmental exposures for patients with IBD. If you have been diagnosed with IBD, please answer the following questions to the best of your ability. You are not obligated to answer every question, though we kindly ask that you answer as many questions as you feel comfortable in giving a response. **All information provided will remain confidential**. We are not asking for any personal identifiers (such as name, date of birth, or social security number), to ensure that your information is also anonymous. You are an invaluable resource in the development of this area of research. Your time, effort, and comments are greatly appreciated. If you have any questions or comments about this study, please contact the Crohn's & Colitis Research Coordinator at the Florida Department of Health, (850) 245-4444 extension 2424.

1. Current age:

2a. Age at Diagnosis of Inflammatory Bowel Disease:
1) 10 or under 2) 11-19 3) 20-39 4) 40-64 5) 65 or older

2b. Time you have lived with the disease in years (or months if less than 1 year):

3. Gender: 1) Male 2) Female

4. Ethnicity: 1) Caucasian 2) African American 3) Asian 4) Hispanic 5) Other:

5. Are you of Jewish descent? 1) Yes 2) No 3) Partly 4) Don't know/unsure

6a. Do you have:
1) Ulcerative Colitis 2) Crohn's Disease 3) Both CROHN'S DISEASE & ULCERATIVE COLITIS 4) Unsure

6b. Where is your disease located?
1) small intestine 2) large intestine 3) both small and large intestines
4) other 5) unsure

6c. Currently, is your disease active? 1) No 2) Yes
If yes, would you say your symptoms are: 1) mild 2) moderate 3) severe

7a. Do you have a family member who is also diagnosed with an IBD?
1) No 2) Yes

7b. If yes, please select all who have been diagnosed:
1) Mother 2) Father 3) Brother 4) Sister 5) Your child/children 6) Other:

8a. Were you born in the United States? 1) Yes 2) No

8b. If yes, what area of the United States were you born?
1) NorthEast 2) SouthEast 3) Midwest 4) NorthWest 5) SouthWest

9. Before you were diagnosed with an IBD, did you live near cattle? 1) Yes 2) No

10. Before you were diagnosed with an IBD, did you smoke cigarettes regularly, meaning on most or all days?
1) Yes-# of years: 2) No

11a. Before you were diagnosed with an IBD, did the other people living in your residence smoke cigarettes? 1) No 2) Yes

11b. If yes, please list the number of years you lived in this residence prior to your diagnosis:

12a. Did you receive a colonoscopy before you were diagnosed with an IBD?
1) Yes 2) No 3) Unsure

12b. If yes, was your first colonoscopy a result of your IBD symptoms?
1) Yes 2) No 3) Unsure

13a. Before you were diagnosed with an IBD, did you have any of the following:

Medical illnesses	1) Yes 2) No 3) Don't know/unsure
Psychological illnesses	1) Yes 2) No 3) Don't know/unsure
Medical hospitalizations	1) Yes 2) No 3) Don't know/unsure
Surgeries	1) Yes 2) No 3) Don't know/unsure

13b. Before you were diagnosed with an IBD, did you have any of these procedures:

Appendectomy	1) Yes 2) No 3)Don't know/unsure
Tonsillectomy	1) Yes 2) No 3) Don't know/unsure
Other (please list):	

14. In general, would you say your health is: 1) Excellent 2) Good 3) Average 4) Poor

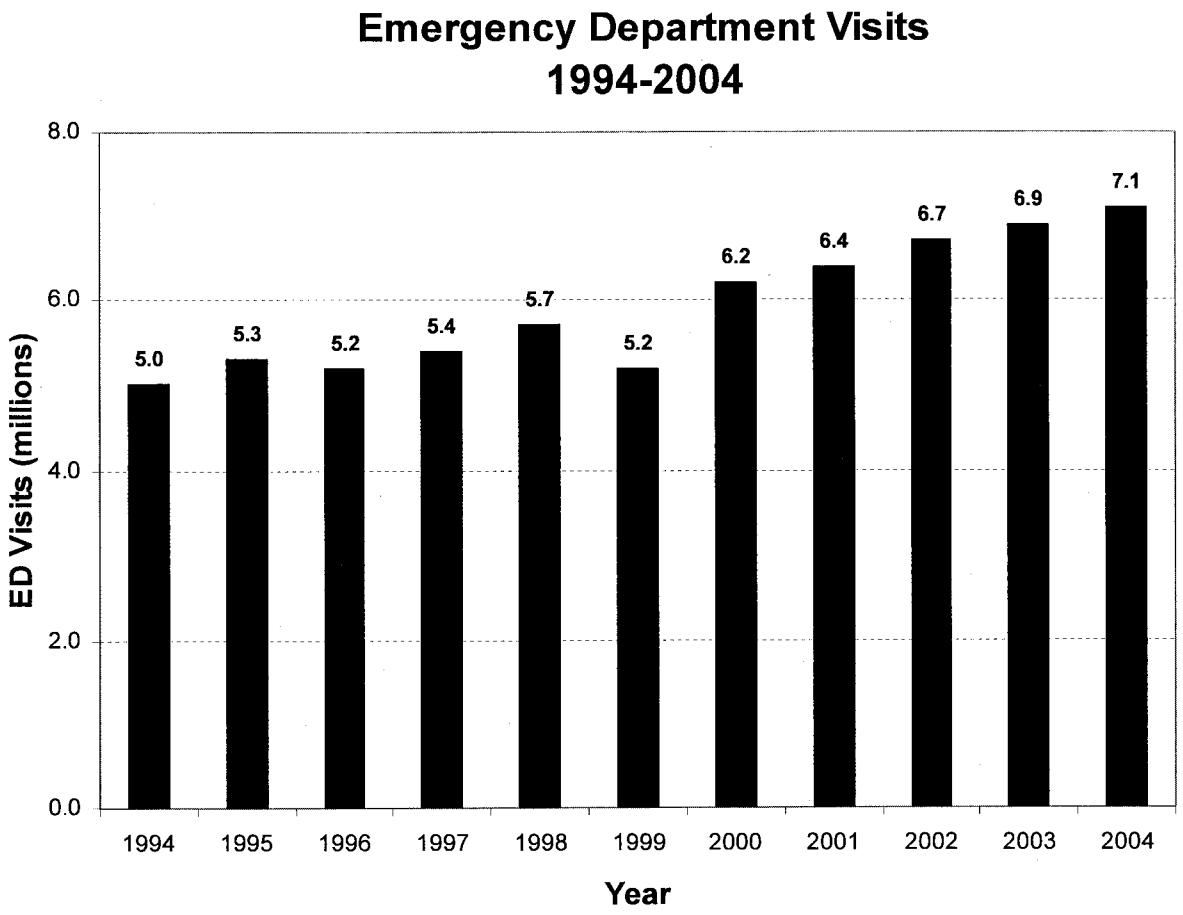
Emergency Psychiatric Care
A Community Crisis

House Health Care Committee
March 8, 2006
Florida Council

Emergency Department (ED) Use The Facts

- In 2004, there were 7.1 million ED visits in Florida; 1.3 million resulted in hospital admissions (AHCA, 2006).
- From 1994 to 2003, visits increased by 26.2% in the U.S. (AHCA, 2006).
- Between 1994-2004, the number of ED visits in Florida increased by 40.9%, while there was a 5.3% decrease in the number of EDs (AHCA, 2006).
- Accounting for increases in population, the visit rate per 1,000 persons increased by 12.9% over the same period (AHCA, 2006).

Florida Emergency Department Visits



Source AHCA Hospital Financial Database

Emergency Department (ED) Use The Facts

- In 2004, total ED charges in Florida were $4.4 billion, a 457.0% increase from 1994 [$791 million]; the average charge per visit was $619 (AHCA, 2006).
- The average ED wait time in Florida is 3 hours (AHCA, 2006); half of ED patients nationally spend 2-6 hours in the ED (CDC, 2005).
- The number of EDs per 1 million people in Florida: 7.82 – 47th in the nation (ACEP, 2006).
- Florida's rank on access to emergency care: C- [41st in nation] (ACEP, 2006); overall Florida ED Rank: C- (ACEP, 2006).
- Nationally, 62% of emergency departments are at or over capacity; one-half of urban EDs are at over capacity (AHCA, 2002).

Emergency Department (ED) Use Psychiatric Disorders

- ED use by those with psychiatric/substance abuse disorders constitutes a significant and growing burden on hospital EDs.
- Two million people visited EDs for psychiatric care in the U.S. in 2002 (NCHS, 2003).
- Many hospital EDs are ill equipped to meet the needs of patients with psychiatric disorders because of inadequate numbers of psychiatric practitioners and beds in many EDs.
- Nationally, from 1992 to 2001, mental health-related ED visits increased from 4.95 to 6.3% of total ED visits and increased from 17.1 to 23.6 visits per 1,000 population (Larkin et al, 2005).

Emergency Department (ED) Use Psychiatric Disorders

- In a 2004 survey conducted by the American College of Emergency Physicians, 60% of physicians reported that the increase in psychiatric ED patients is:
  - negatively affecting access to emergency medical care for all patients;
  - causing longer wait times;
  - fueling patient frustration;
  - limiting the availability of hospital staff; and
  - decreasing the overall availability of ED beds (ACEP, 2006).
- Two-thirds of emergency physicians attribute the recent escalation of psychiatric patients to budget cutbacks and the decreasing number of psychiatric beds (ACEP, 2006).

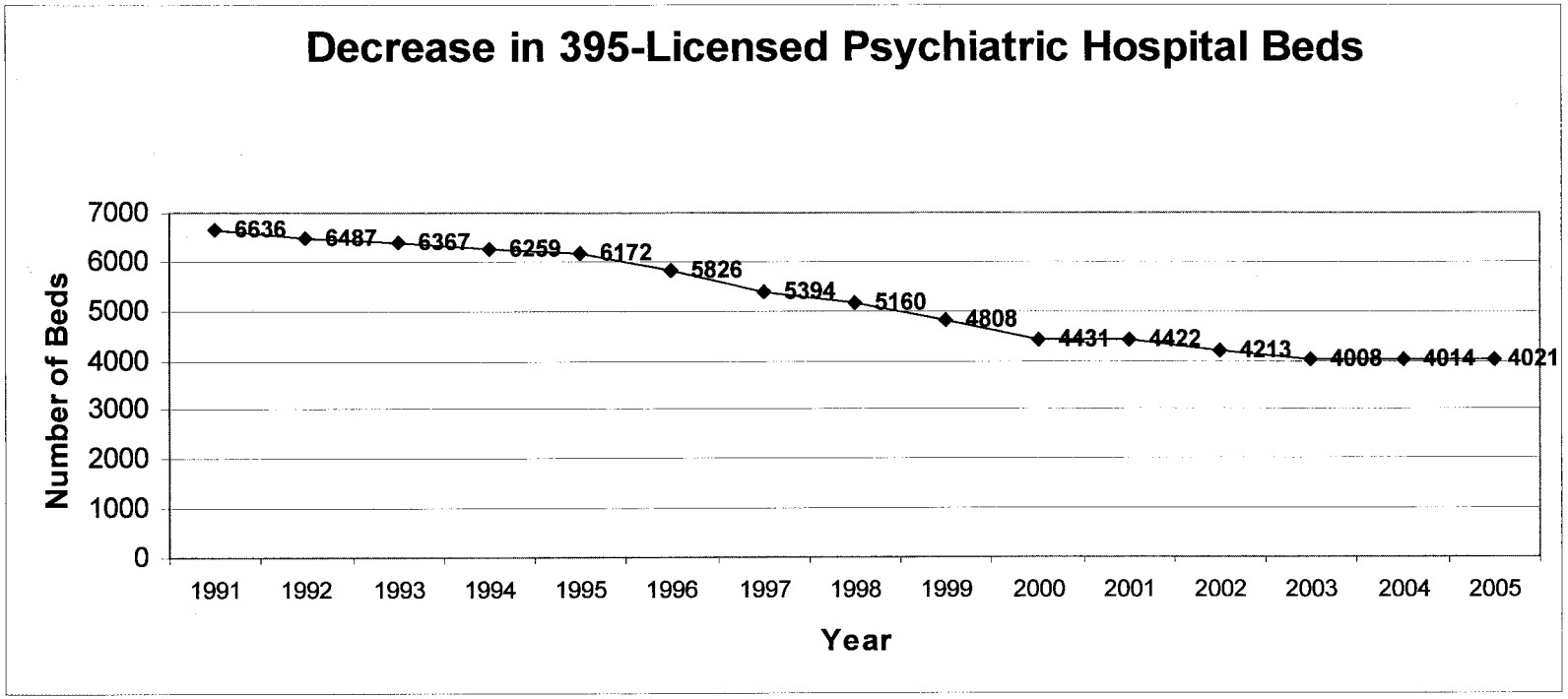
Emergency Department (ED) Use Psychiatric Disorders

- Significant predictors of high ED utilization: prior number of ED visits, prior number of hospitalizations, and history of depression, psychoses, alcohol abuse, and homelessness.
- At a 6.4% prevalence rate, Florida's EDs treat an estimated 1,245 patients with psychiatric disorders every day or more than 454,000 visits/year.
- Homeless individuals account for 30 percent of ED use for psychiatric emergency care; 33% of homeless individuals have one or more ED encounters annually.
- Homeless individuals are more likely than other emergency service patients to have multiple episodes of service and to be hospitalized after the emergency department visit.

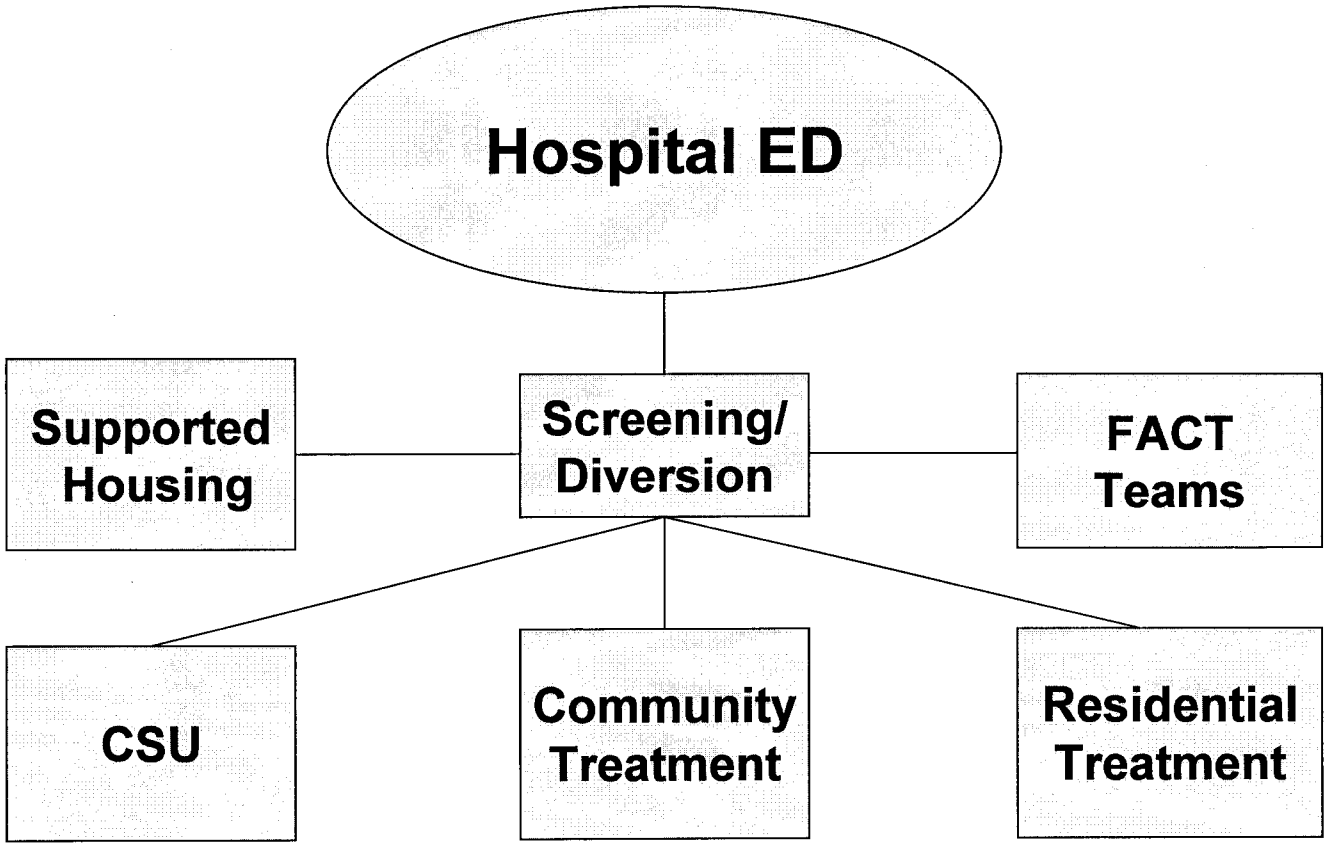
Acute and Emergency Care Issues

- Psychiatric and substance abuse patients represent the 'frequent flyers' and a disproportionate share of total ED visits.
- Increases in ED boarding.
- Reduction in overall psychiatric acute care bed supply and an underfunded publicly financed acute and emergency care system.
- Shortage of CSU and short-term residential beds.
- ED "revolving door" because of lack of post-discharge services.
- Shortage of low-income housing; unstable housing.
- Lack of Medicaid and DCF financed community treatment (crisis and recovery-based services).

Acute and Emergency Care Issues



A New Cost-Effective Approach to Acute and Emergency Psychiatric Care



Crisis Stabilization Units

- Crisis Stabilization Units (CSUs) provide brief psychiatric intervention for low-income individuals with acute psychiatric conditions who are a danger to themselves or others.
- CSU stays average 3 days; 90% of admissions are involuntary and a result of law enforcement intervention.
- CSUs may screen, assess, and admit for stabilization persons who are voluntarily or involuntarily placed pursuant to Chapter 394, F.S.
- Clients may be provided 24-hour observation, medication, and other appropriate services.
- CSUs must provide services regardless of the client's ability to pay and shall be limited in size to a maximum of 30 beds.

Crisis Stabilization Units

- Florida has 45 public receiving facilities with 923 DCF-purchased CSU beds (765 adult beds and 158 children beds); there are 477 Medicaid reimbursable hospital psychiatric beds (306 adults and 171 children's beds).
- DCF estimates that Florida needs 10 CSU beds per 100,000 population.
- Adult Bed Need: 1,395
- Unmet Need: 324 Beds (1,395-[765+306])
- CSU Rates: $292 – no rate increase since 1999 (Recommended rate: $358).
- Additional Funding: $30.6 Million for Beds/$16.1 Million for Rates (75% State-25% Local).

Short-Term Residential Treatment Facilities (SRTs)

- SRTs provide residential care for up to 90 days for individuals experiencing an acute mental health crisis.
- SRT Beds in Florida: 269
- SRT Facilities in Florida: 11
- No SRTs Located in Districts 1, 2, 4, 8, 9, and 13.
- Need: Additional SRTs/SRT Beds

Community Treatment – Unmet Needs

- Prevalence of SPMI Adults: 5.4% (13.9M x .054 = 753,068 x. 33 (SPMI and Seek Treatment – Currently Served [130,702]).
- Unmet Adult Need: 120,070
- Prevalence of SED Children: 7.9% (4.1M x. .079 x .286 (uninsured) x .36 require public coverage.
- Unmet Child Need: 161,654 (207,205- 45,551 [currently served])
- $ Needed: Adults - $136.9M; Children - $97.0M
- Florida ranks 47th in per capita state spending on mental health care.
- ED use drops by 50+% with community treatment.

Assertive Community Treatment

- Florida has 32 FACT Teams.
- The annual cost of a FACT Team is $1,254,394; total appropriation is $40.1 million.
- Each team serves 100 individuals; 60% are Medicaid eligible.
- Total FACT Team capacity statewide – 3,200 individuals; average monthly caseload in 9/05 was 2,844 – 94% of statewide capacity.
- ACT Findings: ED use down 32-50%, hospitalization down 58-78%; ACT highly successful in engaging individuals in treatment, increasing housing stability and improving symptoms.
- Needs: Additional FACTs (Adult, Children, Forensic) and Rate Increases.

Model Programs

- San Francisco General Hospital Frequent User Program/ED Case Management Program/Crisis Resolution Team
- Boston Health Care for the Homeless Project
- Comprehensive Psychiatric Emergency Programs (Maryland, New York)
- Psychiatric Emergency Response Team/Services (Multiple Sites)
- Orlando Community Receiving Center
- Mobile Crisis Teams (Multiple Sites)
- Crisis Family Care (Multiple Sites)
- Crisis Care Center (San Antonio)
- Assertive Community Treatment (Multiple Sites)
- Jail Diversion Programs (Multiple Sites)

Recommendations

- Assess Acute and Emergency Psychiatric Care Needs in Florida; Determine Effect of Psychiatric Emergency Care on ED Overcrowding
- Expand CSU Capacity – Increase Beds/Increase Rates
- Expand Short-Term Residential Capacity
- Expand FACT Teams
- Close the Treatment Gap/Achieve Funding Equity
- Increase Permanent and Supported Housing
- Create Integrated Systems of Care